The Royal College of Pathologists

The retention and storage of pathological records and archives (3rd edition)

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

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This third edition was approved by Council in January 2005, subject to consultation. In accordance with the College's publications policy, it was then placed on the Fellows' and Members' area of the College website for consultation from 21 January to 21 February 2005. Eleven people submitted detailed comments. Professor Peter Furness and the Working Group considered the feedback and amended the document accordingly. Please email publications@rcpath.org if you wish to see Professor Furness' responses to the feedback received.

Professor John A Lee
Director of Publications

Updates since publication of the 3rd edition

8 April 2005 Newborn blood spot screening cards. Paragraph 72 and Bibliography.

18 August 2005 Coagulation samples. Paragraph 73.

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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*. It was approved by College Council, subject to consultation, in January 2005.

References to the Human Tissue Act 2004 in this document are made on the assumption that the provisions of the Act have been implemented. This is expected to occur in April 2006.

The Human Tissue Act does not apply in Scotland, but parallel legislation is planned relating to authorisation of hospital post-mortem examinations. Where the situation in Scotland is likely to differ, this is indicated, and it is the intention of the College to update its advice when the precise form of the Scottish legislation is known. Meanwhile, pathologists working in Scotland should be aware of the NHS Quality Improvement Scotland standards for the management of post-mortem examinations, published in March 2003.

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.

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

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Background to the 2005 revision

The few years since the 1998 revision of this document have seen rapid 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. The most public manifestation of this change has been the publicity surrounding concerns about the retention of tissue removed at post-mortem in hospitals in the UK. This has led to the introduction of the Human Tissue Act 2004. But even prior to this, a change in society's attitudes 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.

These changes have required modifications in the advice of the College on the retention and storage of pathological records and archives. However, the modifications are perhaps less extensive than might be expected.

In most cases, the records and archives are held primarily for the benefit of 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 for this purpose (unless the tissue is obtained at post-mortem). In relation to data protection law, it is reasonable to infer that the information held in the 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 infer that pathologists have legitimate authority to retain records and archives for the benefit of the patient, relying only on the consent that was a clinical requirement for their original generation.

References in the 1998 guidance to retention specifically for purposes *other than* the direct benefit of the patient concerned have therefore been modified by the need for appropriate consent for retention for many such purposes.

It also 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 such destruction. Laboratories should have an established procedure on how to inform such patients of such possible adverse consequences, and the potential health hazards associated with human tissue samples. However, if a patient thus informed still insists on destruction, consent has been explicitly withdrawn and destruction or return must occur.

The situation in Scotland relating to blocks and slides created from samples from the living is different. The Scottish guidance that is currently being devised 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 archives, *not* their use.

This document does not cover material stored for therapeutic uses, such as transfusion or transplantation, though 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 legitimate or illegitimate. When using archives 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. 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 in respect of data or the Human Tissue Authority in respect of human biological samples.

Whenever such advice is sought, the presence and nature of consent, even if only implied 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. A requirement to re-contact patients for consent long after the clinical event is rarely practical or ethical, so if contemporaneous consent is not requested and recorded, valuable work could be blocked. Where such procedures are not in place, pathologists should argue for their introduction, because they have become a requirement for some types of activity (especially the use of tissue and data in research) even if the work produces no risk to the patient and is intended for the benefit of all in society.

THE SCOPE AND NATURE OF PATHOLOGY RECORDS

i) Clinical and diagnostic records and reports

1. These are hard copy reports 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 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. 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 HSG 1999/053 (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) (see Bibliography). In Scotland, the position is set out in MEL(1993)152, which is currently in the process of revision.

2. Until the Departments of Health have clarified the position on the retention, storage and legal validity of electronic patient records, hard copy reports of pathological investigations for these categories of patients should be incorporated in their individual clinical records and (although

there is no obligation to destroy them at all) patient records may not be destroyed until the minimum period for retention has elapsed.

3. Point-of-care testing (POCT) services should be provided and operated in accordance with recommendations from the Medical and Healthcare products Regulatory Agency (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 that apply to a pathology laboratory should also apply to the POCT service.

ii) Laboratory records: reports, documentation

4. These include request forms; protocols of procedures; day books; worksheets; batch records; graphic output from instruments; photographic records; catalogues of the pathological archive/museum; bound copies of reports/records; near-patient test data; correspondence; records of telephoned reports; equipment maintenance logs; quality control and quality assurance records; standard operating procedures; accreditation documents and records of inspections.

5. Where these items are held in electronic form, usually as digital images, the same criteria that cover conventional records apply. However, extra care is needed to prevent corruption or deterioration of data. Suitably secure backup systems should be employed. As equipment becomes obsolete, re-recording or the production of durable hard copy may become necessary.

iii) Specimens

6. These include stored human biological specimens such as serum, tissues, 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 for phenylketonuria, the Guthrie test card); microbiological cultures, freeze dried or otherwise preserved.

7. When the term ‘tissue’ is used in this document, it is used broadly in parallel with the definition in the Human Tissue Act 2004, i.e. material containing human cells. However, this document is not limited to such material, as it includes reference to acellular human biological material such as serum and plasma. Such material is not covered by the Human Tissue Act, but the professional requirement to adhere to relevant ethical requirements should nevertheless be regarded as binding.

THE MANAGEMENT OF RECORDS AND ARCHIVES: GENERAL COMMENTS

8. Diagnostic records are properly retained in individual patient notes or in electronic form. The safe keeping of these records is 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.

9. Where storage of material is no longer required for clinical purposes, but is desirable for teaching, 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. Research use will also require Research Ethics Committee approval.

10. 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 are legally permissible without patient consent, largely because they are regarded as a necessary part of the process of providing healthcare.

    a) Further diagnoses, or ongoing clinical management.
    b) Clinical audit and quality control.
    c) Teaching and training healthcare staff.
    d) Epidemiology.
    e) Analysis of data (such as case mix) for administrative or other purposes.
    f) Direct evidence in litigation.
    g) Research where data or samples are suitably anonymised **and** Research Ethics Committee approval has been given for the purpose.

11. It is nevertheless appropriate, if it is practical, to check that the patient has not lodged a specific objection to such use.

12. In areas where the Human Tissue Act 2004 will apply, retention without appropriate consent of specimens obtained at post-mortem is not permissible unless under one of the exclusions specified in the Act, notably under the authority of the Coroner or for the requirements of the criminal justice system. Under the Human Tissue Act, authority to store human tissue for a scheduled purpose without consent does **not** persist after the Coroner's work is complete, but 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.

13. The following reasons are acceptable reasons to retain samples and data only if 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, or the Human Tissue Act, e.g. as a result of procurement before the Act came into force).

    a) Research (other than that covered by point (g) above).
    b) Historical purposes.
    c) Holding of pathological material and records in specialised banks.
    d) Nationally recognised reference practice.

14. 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.

15. 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.

16. 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.

17. 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. Where the retention of human tissue is unlawful, anonymisation does not make its continued retention lawful (unless for ethically approved research). This is particularly relevant to material obtained at post-mortem.

18. **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 pathologists will have good and cogent reasons for retaining records and materials for much longer periods.

19. Where laboratories or hospitals are to be closed, we recommend that pathologists discuss with responsible managers 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. This will necessitate careful organisation, but also provides opportunity for disposal of unneeded records.

20. It is 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 *vs* 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 halted as to the documents or specimens relevant to that matter.

21. **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. 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.

22. In previous 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 clarity, this version uses the phrase 'for at least 30 years'. 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 HSC199/053). 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.)

23. 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.

24. 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

25. 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.

26. 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 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 unless the information is transcribed to another source (such as a computer record). Where regarded as minor financial documents for cross-funding purposes, the advice of the local finance department should be sought.

Day books and other record of specimens received by a laboratory

27. Two calendar years.

Protocols of standard operating procedures

28. Both current and outdated protocols should be dated and kept at least 30 years on file.

Worksheets

29. Keep for same length of time as related permanent or semi-permanent specimens or preparations.

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

30. Two calendar years.

Records of telephoned reports

31. Log on the laboratory record of the relevant report or hard copies kept for two calendar years.

Reports, copies

32. Six months for operational purposes.

Surgical (histological) reports

33. Copy lodged in patient's notes. Electronic or hard copy kept at least 30 years by the laboratory.

Post-mortem reports

34. 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 kept at least 30 years. (See also Section D)

Correspondence on patients

35. Should be lodged in patient's record. Otherwise, keep at least 30 years.

Near-patient test data

36. Results should be entered on patient's record; log should be retained for lifetime of instrument.

Bound copies of reports/records, if made

37. At least 30 years.

Pathological archive/museum catalogues

38. At least 30 years, subject to consent where required.

Photographic records

39. Where images represent the primary source of information for the diagnostic process, whether conventional photographs or digital images, they should be kept at least 30 years. In practice, this will represent material from which neither the primary tissue(s) nor subsequent tissue blocks, slides or cell suspensions have been stored.

40. 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.

41. 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 at least 30 years.

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

Batch records results

43. At least ten years.

Internal quality control records

44. At least ten years.

External quality assurance records

45. Subscribing laboratories or individuals: two calendar years. Records will be kept for longer periods by quality assurance laboratories.

Accreditation documents; records of inspections

46. Ten years, or until superseded.

Equipment maintenance logs

47. Lifetime of instrument; minimum ten years.

Records of service inspections, maintenance of instruments

48. Lifetime of instrument; minimum ten years.

Records relevant to production of products (diagnostics) or equipment

49. Comprehensive records relevant to procurement, use, modification and supply: 11 years.

Research data

50. See below.

Records relating to organ transplantation

51. Records not otherwise kept or issued to patient records that relate to investigations or storage of specimens relevant to organ transplantation should be kept at least 30 years.

Records relating to retention of semen or ova

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

B SPECIMENS AND PREPARATIONS

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

Legal issues

53. Note that under the Human Tissue Act 2004, storage of any material containing human cells, including fluid samples, for a scheduled purpose (see Appendix A) is likely to be a criminal offence unless undertaken on premises that have an appropriate license from the Human Tissue Authority. Precise details of the licensing requirements will be published in regulations and guidance to be issued under the Act during the course of 2005. The position in Scotland is somewhat different, and is set out at the end of this section.

54. Under the Human Tissue Act, neither consent nor a license are required for the storage of material for diagnostic purposes for the benefit of the person from whom the tissue was removed during life.

55. Appropriate consent (as defined in the Act and by the Human Tissue Authority) is required for storage for purposes listed in part 1 of Schedule 1 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 at post-mortem examination (see Appendix A).

56. 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 the Coroner's duties are complete and hence for how long the retention of relevant tissue samples should be authorised, so the instructions of the Coroner should be obtained and followed.

57. 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. There appears some uncertainty regarding the point when the functions of a Coroner have been completed. It has been argued that the Coroner cannot authorise retention extending beyond either the completion of pink form B or the conclusion of an inquest, but that is not a matter for the pathologist. 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.

58. Samples may be retained by or at the instruction of other agencies (e.g. the police) for as long as they are required for the purposes of investigation of crime or for the criminal justice system. The pathologist is advised to seek from those other agencies the precise legal authority underlying the request for retention to ensure that the provisions of the Human Tissue Act are not breached

59. However, 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 A).

60. 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 A).

61. **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 that retention of organs, tissues blocks and slides after post-mortem is primarily for the Fiscal's purposes in seeking to determine the cause, mode and related circumstances of the death. There are, however, reasons for retaining the material where the diagnosis is in doubt, or where it is an unsolved criminal case that may need to be looked at again. Access to archived material is, in these cases, essentially a matter of future diagnosis, and no authorisation is required from the relatives in respect of retention for these purposes.

62. It is current practice for tissue blocks and slides to be retained routinely following a Fiscal post-mortem examination. The present basis of such retention, once the Fiscal's purposes have been satisfied, is unclear, but there is general agreement on the value of retaining such material as part of the individual's medical record, and for research, audit of forensic practice and educational purposes. The new human tissue legislation proposed for Scotland will therefore contain a provision deeming such tissue blocks and slides to be part of the medical record once the Fiscal has indicated he or she no longer requires them, and this will allow their use for diagnostic and audit purposes without authorisation from the family. As part of those arrangements, a standard authorisation form has been devised, but not yet put into practice. 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. Until the new legislation and standard authorisation form have been brought into effect, there is no objection to tissue blocks and slides being used for such purposes, provided a means has been found of confirming that the family agree to such use.

63. Organs retained at a Fiscal post-mortem examination will 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.

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

Plasma/serum

65. Forty-eight hours after final report has been issued by the laboratory.

66. In cases of transplantation, donor/recipient sera, with the records pertaining, must be kept for 11 years post-transplantation.

67. Serum from the first pregnancy booking visit should be kept for one year by microbiology/virology laboratories to provide a baseline for further serological or other tests for infections or other disease during pregnancy and after delivery.

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

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

70. Other leftover sera or plasma should be stored for as long as practicable to provide an array of material for future research and disease surveillance purposes. Samples that do not contain human cells are not regulated as human tissue by the Human Tissue Act, though 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.

71. See also Section C.

Newborn blood spot screening cards

72. A minimum of five years storage 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 Bibliography.

Body fluids/aspirates/swabs

73. Forty-eight hours after the final report has been issued by the laboratory, unless sample deterioration precludes storage; e.g. coagulation samples may be discarded after 24 hours. Samples that are easily and non-invasively repeated, such as most urine samples, may be destroyed as soon as the examination is concluded.

Whole blood samples, for full blood count

74. Twenty-four hours.

Frozen tissue for immediate histological assessment (frozen section)

75. Stained microscope slides should be kept as below. 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

76. At least ten years, preferably longer if storage facilities permit. This advice includes EBV-transformed and fibroblast cell lines. At least three months (longer if space permits) for cytogenetic cell suspensions in fixative.

Paraffin blocks

77. At least 30 years if storage facilities permit. If not, select representative blocks, showing main pathology, for permanent retention and review the need for archiving at ten years and at intervals thereafter.

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

79. Early destruction of blocks from paediatric cases is inappropriate; these should not be destroyed until the child is at least 25 years old.

80. Special considerations apply in forensic practice; see section D.

81. Post-mortem blocks must only be taken, stored and used in accordance with the consent obtained for post-mortem. In the case of tissue taken during a post-mortem for the Coroner or Fiscal, the guidance under 'Legal issues' at the head of this section should be followed. It should be noted that the situation in Scotland differs from that in the rest of the UK. The nature of consent for retention of all post-mortem tissue should be documented, and that documentation should be retained for as long as the specimens are retained.

Blocks for electron microscopy

82. At least 30 years.

Grids for electron microscopy

83. Ten years, preferably longer if practicable.

Wet tissue (representative aliquot or whole tissue or organ)

84. For surgical specimens, four weeks after final report.

85. 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, use and disposal.

86. In the case of post-mortem samples retained before the implementation of currently acceptable consent procedures, the advice of the Retained Organs Commission (*Good Practice Guidance* – see Bibliography) should be followed, at least until updated advice is available from the Human Tissue Authority on suitable procedures for their use or disposal.

87. In Scotland, a formal five-year period began on 18 April 2002 under which families are 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 has accepted the recommendation of the Review Group on Retention of Organs at Post-Mortem that organs and tissue unclaimed at the end of the five years should be legally deemed to come under the authority of the relevant hospital, which should be able to make use of it for legitimate research or educational projects. Where organs or tissues are not considered necessary or suitable for those purposes, the hospital should

ensure their respectful disposal. The Executive has 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. New research projects have been able to begin since 18 October 2002 using material retained under past practice. All such projects must be non-destructive 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)

88. Permanently (provided there is no deterioration, or until replaced by a better specimen). Appropriate consent is a legal requirement under the Human Tissue Act for the retention of tissue for teaching purposes, only if the tissue was obtained during a post-mortem examination. Nevertheless, it is good practice to obtain consent from living patients before entering preserved surgical specimens into a museum.

89. Advice on the storage and use of museum specimens obtained before the implementation of the Act is expected from the Human Tissue Authority.

90. If specimens are stored under conditions that can be regarded as representing public display, the Human Tissue Act requires that consent must be in writing, witnessed and given by the patient. The consent of a relative is not appropriate to sanction public display.

Stained slides

91. Appropriate retention times depend on their purpose.

    a) Microbiological: seven days after final report.

    b) Blood films, routine: seven days after final report.

    c) Cytogenetic preparations: two years after final report, if photographic or digitised record kept; five years otherwise. If photographed or digitised, the image should be stored for 30 years.

    d) Molecular cytogenetic preparations (e.g. fluorescence *in-situ* hybridization [FISH] slides). A representative photographed or digitised image should be captured for all patients and stored for 30 years. Long-term storage of FISH slides is problematical, but these should be retained at least until the final written report has been authorised and issued.

    e) Bone marrow smears: 20 years minimum; ideally over the lifetime of the patient.

    f) Cytology, including population screening: ten years minimum; longer if possible, to cover at least one recall visit.

    g) Histology: ten years; longer if practicable. It should be realised that retention of the paraffin block alone does not always guarantee the retention of relevant diagnostic material, especially with small biopsies. If the disposal of slides at ten years is contemplated, it may be appropriate to select slides from small biopsies for longer retention.

Human DNA

92. A minimum of four weeks after final report for diagnostic specimens; at least 30 years if needed for family studies in those with genetic disorders. With limited exceptions, it is an offence under the Human Tissue Act merely to possess human DNA if there is an intention to undertake non-

consensual analysis. Accordingly, the need for retention of diagnostic specimens should ideally be assessed at the time of sampling, and appropriate consent obtained. Specimens that were used in research should be kept at least 30 years if the consent status permits it.

Microbiological cultures

93. Most positive cultures can be discarded within 24–48 hours of issuing a final authorised report. Specified cultures of clinical importance (blood culture isolates, cerebro-spinal fluid (CSF) 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 seven days. Where isolates have been referred to reference laboratories, they should be retained for at least seven days after the issue of their final report.

94. 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.

Freeze dried or other permanently preserved cultures

95. Permanently where archived in collections accessible for study, such as those nationally or locally recognised.

Electrophoretic strips and immunofixation plates

96. Five years, unless digital images are taken. If digital images of adequate quality for diagnosis are taken, then the original preparations may be disposed of after two years. The images should than be stored as discussed above under 'Photographic records', bearing in mind the need to maintain the ability to read archived digital images as 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

97. One month.

Worksheets

98. Documentation to allow full traceability of all blood products used must be kept for at least 30 years (EU Directive 2002/98/EC). The data may be in electronic form if robust archiving arrangements are in place.

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

99. Thirty years, in compliance with EU Directive 2002/98/EC (see Bibliography).

Blood Bank Register, blood component audit trail and fates

100. Documentation to allow full traceability of donor and recipient must be kept for at least 30 years (EU Directive 2002/98/EC). The data may be in electronic form if robust archiving arrangements are in place.

Refrigeration and freezer charts

101. Eleven years.

Annual reports (where required by EU Directive 2002/98/EC)

102. Fifteen 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

103. One week at 4°C.

Separated serum/plasma, stored for transfusion purposes

104. No minimum storage time is recommended for patient (recipient) samples. Storage should optimally be at -30°C or colder. May be stored for up to six 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 three years, preferably longer if it is practicable, in order to facilitate 'look-back' exercises.

D FORENSIC MATERIAL

Criminal cases

105. In cases where criminal proceedings are anticipated, all recordings made at the autopsy, be they hand notes (by everyone, i.e. pathologist, trainee, etc.), tape recordings, drawings or photographs, are all documentary records and as such must be declared (disclosed) to exist and kept permanently. They must be available to all involved in the lifetime of the case. They are not normally entered in the patient records.

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

106. 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.

E GENETICS

107. 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.

108. 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

109. 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 at least 30 years. 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 clinically relevant sequence and polymorphism information.
- Storage of dosage profiles (MAPH/MLPA).
- Storage of autoradiographs, SSCP,PTT DGGE (heteroduplex) gels.
- Other agarose gels.
- Storage of clinically relevant mutation and polymorphism information.

B Molecular cytogenetics

- Storage of all FISH imaging data both qualitative (e.g. microdeletion test) and quantitative (e.g. CGH).
- Storage of Array-CGH data.
- All other diagnostic outputs associated with detection of genomic dosage imbalances.

DISPOSAL OF HUMAN TISSUE

110. 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. It is anticipated that the new Human Tissue Authority will issue guidance for England, Wales and Northern Ireland, but at present that which follows also applies to Scotland.

111. Disposal of liquid samples 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 waste.

112. Where patients have indicated, within the normal time limits for retention of samples, a wish for the return of unprocessed material, their request 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

113. Currently foetal remains of less than 24 weeks' gestation are not defined as human remains and are therefore outside of current burial and cremation legislation.

114. Laboratories should have a policy for the disposal of samples containing foetal parts. This 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*[1]) and the Department of Health document '*Q and A on Disposal following Pregnancy Loss Before 24 Weeks Gestation*', though this advice is likely to be replaced by guidance produced by the Human Tissue Authority in due course.

115. 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 guidelines provided by the Institute of Cemetery and Crematorium Management are adhered to (see Bibliography).

116. It is good practice for clinical staff to ask the mother to provide written 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 private funeral should be offered. Where the wishes of the parents are known, they should be followed.

117. 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.

118. Where doubt exists, advice should be sought. The advice of the hospital chaplaincy service or a clinical ethics committee (if available) may be of value.

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[1] This document had not been published by The Royal College of Obstetricians and Gynaecologists at the time of writing; a final draft has been reviewed and publication is expected in early 2005.

MEDICO-LEGAL VALUE OF ARCHIVED MATERIAL

119. 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.

120. 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 microfiche 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.

121. Archived material is important for 'look-back' exercises, where an 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 many circumstances, the material used must 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.

TEACHING RECORDS

122. Selected photographs, preserved cultures, mounted specimens and stained slides, with the blocks pertaining 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. The identity of the patients should be protected by irreversible anonymisation or, as a minimum, a secure coding process.

123. 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.

RESEARCH DATA AND RECORDS

124. Confidential named patient data (documentation) collected in the course of investigation and held separately from patients' records should be destroyed or anonymised six months after the research has been completed, the data has 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.

125. Working records and other research data should be retained for at least ten years to rebut allegations of scientific fraud, but wherever possible these records should not include patient-identifiable data unless consent for such retention has been obtained. Records and clinical trial data on medicines must be kept for 15 years. The provisions of the Data Protection Act (1998) must be observed for these as for other pathological records.

CONFIDENTIALITY OF RECORDS

126. The General Medical Council instructs: "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".

127. 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. 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.

128. Confidential data transmitted electronically, especially over the internet, must be assumed to be liable to interception and therefore must be encrypted. The most suitable method of encryption will vary with the circumstances and over time, but pathologists should be aware that if confidential information is decrypted by an unauthorised person, it is likely to be taken as evidence of negligence.

129. 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 items (e.g. cultures of viable organisms) may need to be stored in locked containers and in secure laboratory premises with restricted and controlled access. Very valuable records may need to be kept in fireproof containers.

LONG-TERM (PERMANENT) RETENTION OF RECORDS

130. 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). In Wales, the definitive circular on Managing Records in Trusts and Health Authorities is WHC(2000)71.

131. Pathologists 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, or unless the

records under their immediate care are already secured in an approved place of deposit. Records (logs) of authorised destruction may be helpful, but are not mandatory.

132. 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 under HSC 1999(053) (other than in Scotland, where MEL(1993)152 applies).

133. Usage 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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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: 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.