



SCOTTISH EXECUTIVE

Health Department

Dear Colleague,

HUMAN TISSUE (SCOTLAND) ACT 2006: A GUIDE TO ITS IMPLICATIONS FOR NHSSCOTLAND

This Act replaces for Scotland the provisions of the Human Tissue Act 1961, which dealt with transplantation and post-mortem examinations. It also modernises the provisions of the Anatomy Act 1984 as they relate to Scotland.

The new legislation introduces the concept of 'authorisation', and in doing so embodies the principle that people can expect the wishes they express during life about what should happen to their bodies after death to be fulfilled.

The 2006 Act is essential to our aim of increasing organ donation rates in Scotland. It is also fundamental to a restoration of confidence in the post-mortem examination. Both of these aims will be achieved only if there is widespread co-operation in implementing the provisions of the Act. I would urge you to play your part in helping us to secure the maximum benefits from this important piece of legislation.

Yours sincerely,

KEVIN WOODS

Head of Health Department and Chief Executive, NHSScotland

20 July 2006

Addressees

For action

Chief Executives, NHS Boards
Chairs and Directors, Regional
Planning Groups
Medical Directors, NHS Boards (and
to cascade to Practice Managers)
Nursing Directors, NHS Boards
Director of Tissue Services, SNBTS
CHP Managers
Independent Hospitals in Scotland
Chief Executive, Human Tissue
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For information

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HUMAN TISSUE (SCOTLAND) ACT 2006: A GUIDE TO ITS IMPLICATIONS FOR NHSSCOTLAND

INTRODUCTION

1. The Human Tissue (Scotland) Act 2006 (referred to in this HDL as ‘the 2006 Act’) deals with 3 distinct uses of human tissue: its donation primarily for the purpose of transplantation, but also for research, education or training and audit; its removal, retention and use following a post-mortem examination; and for the purposes of the Anatomy Act 1984 as amended for Scotland by the 2006 Act. This HDL sets out, for each of these purposes, the key points which affect NHSScotland, especially in terms of the preparations which need to be made before 1 September 2006, when the substantive provisions of the whole Act will be brought into operation. It also explains the links, where appropriate, to the new legislation for the rest of the UK, the Human Tissue Act 2004, the bulk of which is also being commenced on 1 September 2006.

2. The text of the Act (2006 asp 4) can be found at the website of the Office of Public Sector Information (OPSI) (www.opsi.gov.uk/legislation/scotland/about.htm), along with detailed Explanatory Notes. The 2006 Act is supplemented by a number of Regulations and Orders, as follows:

- the Human Tissue (Removal of Body Parts by an Authorised Person) (Scotland) Regulations 2006 (SSI 2006 No. 327);
- the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (SSI 2006 No. 390);
- the Adults with Incapacity (Removal of Regenerative Tissue for Transplantation) (Form of Certificate) (Scotland) (No. 2) Regulations 2006 (SSI 2006 No. 368);
- the Human Tissue (Scotland) Act 2006 (Maintenance of Records and Supply of Information Regarding the Removal and Use of Body Parts) Regulations 2006 (SSI 2006 No. 344);
- the Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons) (Scotland) Order 2006 (SSI 2006 No. 310);
- the Human Tissue (Specification of Posts) (Scotland) Order 2006 (SSI 2006 No. 309);
- the Anatomy (Specified Persons and Museums for Public Display) (Scotland) Order 2006 (SSI 2006 No. 328);
- the Anatomy (Scotland) Regulations 2006 (SSI 2006 No. 334); and
- the Human Tissue (Scotland) Act 2006 (Anatomy Act 1984 Transitional Provisions) Order 2006 (SSI 2006 No. 340).

The text of these Regulations can also be found on the OPSI website.

ORGAN DONATION AND TRANSPLANTATION

3. Part 1 of the Act begins by placing a duty on the Scottish Ministers to promote, support and develop programmes of transplantation, to promote information and awareness about the donation for transplantation of parts of a human body, and to promote the taking of any necessary measures relating to the quality and safety, storage and use of any body part donated for the purpose of transplantation (section 1). Section 2 allows the Scottish Ministers to give assistance and support, including financial assistance, to anyone providing, or proposing to provide, a service relating to transplantation.

4. There are a number of aspects to these duties and powers. Scotland already has programmes of transplantation for all the main solid organs, and for all types of tissue. The 2006 Act allows for the development of new programmes, particularly through its use of the words 'body parts', which gives full scope for the introduction at any time in the future of new types of transplantation such as hand or face transplants. This will allow Scotland to remain at the forefront in benefiting from advances in transplantation techniques.

5. The Scottish Ministers and NHSScotland already support programmes of transplantation not only financially but through an ongoing series of advertising and publicity campaigns. In debating the legislation, the Parliament expressed strong support for the funding of this work, which is seen as essential to helping boost organ donation rates in Scotland. The Executive fully intends to continue this work, which is aimed at increasing the number of people who, during their lifetime, express a wish to donate parts of their own body after death to save or transform the lives of those waiting for a transplant. In addition, the Executive intends to continue its work of raising public awareness of issues relating to organ and tissue donation and transplantation, and will in particular revise its Teaching Resource Pack, which is aimed at senior school pupils and which has been evaluated very positively. The Executive is also working with the UK Transplant Division of NHS Blood & Transplant (UKT) to update the various forms currently in use which allow people to register their wishes on the NHS Organ Donor Register.

6. The Executive also considers that the duty to promote information and awareness about donation for transplantation, combined with the principle of authorisation (see paragraph 8 below) place a responsibility on NHSScotland to respect people's wishes. Where NHS staff are aware that someone has expressed a wish to donate, they should take whatever steps are open to them to ensure that those wishes can be fulfilled. Doctors in particular will be aware that the GMC's guidance now includes a duty to respect the wishes of patients after their death. For those not directly involved in transplantation services, discharging the duty under the Act would probably mean making sure that there was a clear awareness and understanding of the person's wishes. For those directly involved with transplantation, it means making sure the person's known wishes are acted on.

7. The Executive also wishes NHSScotland collectively to consider the current infrastructure and resourcing for organ donation and transplantation, since the experience of Spain and Tuscany suggests that these are key factors in determining organ donation rates. The Executive is aware that there will be close Parliamentary scrutiny of the effect of the legislation in increasing these rates in Scotland, and has asked the Scottish Transplant Group to work with the various agencies involved, including NHS Boards, the Regional Planning Groups, the National Services Division of NHS National Services Scotland, the Tissue Services Division of the Scottish National Blood Transfusion Service, UK Transplant and the Human Tissue Authority to consider the optimum arrangements for Scotland.

Transplantation from deceased donors

8. The 2006 Act represents a strengthening of the current system of 'opting in', as does the Human Tissue Act 2004 which applies to the rest of the UK. The 2006 Act is based on the principle of 'authorisation', an expression which is intended to convey that people have the right to express, during their lifetime, their wishes about what should happen to their bodies after death, in the expectation that those wishes will be respected. It is a positive concept, representing a positive attitude to the issue, and replaces the 'lack of objection'

approach embodied in the Human Tissue Act 1961, which the 2006 Act repeals for Scotland. Authorisation equates to the principle of ‘consent’ on which the Human Tissue Act 2004 is based. The equivalence of the 2 principles is an essential part of the continuation of the arrangements for sharing organs and tissue across the UK in order to obtain the best outcomes for recipients.

9. The authorisation arrangements set out in the 2006 Act apply in the transplantation and hospital post-mortem examination contexts and relate to 3 categories: adults (ie those aged 16 or over who have the capacity to make their own decisions about these matters), children aged 12 or over at the time of their death, and children who died aged less than 12. The formalities of authorisation will be set out in the new forms which transplant co-ordinators will require to use once the provisions of the 2006 Act come into effect, and the Executive is currently working with UK Transplant on the content of those forms.

10. Section 6 of the 2006 Act provides that adults can authorise the removal and use of a part of their own body after their death for the purpose of transplantation, as well as for the purposes of research, education or training and audit. In most cases, transplantation will be the purpose which motivates people to record their wishes, and this will most likely take the form of deciding to carry an organ donor card or adding their name to the NHS Organ Donor Register. Any other form of authorisation will however be valid, whether it is in writing or expressed verbally. The terms of section 6 have been drafted so as to permit registration on the NHS Organ Donor Register either online or over the telephone, as well as the arrangements developed by SNBTS for obtaining agreement over the telephone to use of tissue for transplantation purposes. From 1 April this year, UKT has introduced a system of acknowledging such registrations, as part of a range of measures intended to ensure their authenticity.

11. Section 15 makes clear that any wishes relating to transplantation which an adult made before 1 September 2006 will count as if they were authorisations under the new legislation, whatever process of registration was used. This avoids the need in particular for adults to renew their organ donor card or to put their name again on the NHS Organ Donor Register. Section 22 of the 2006 Act stipulates that an authorisation by the adult in favour of transplantation takes precedence over any authorisation which the adult may have left for any of the other purposes covered by the Act. This reflects the life-saving nature of most transplantation activity.

12. An adult can withdraw authorisation for transplantation, and for any of the other purposes mentioned in paragraph 10, at any time, but must do so in writing so that there is complete clarity about which wishes should prevail at the time of the adult’s death.

13. The 2006 Act deals with the mechanisms for acting on the expression of wishes in favour of donation and transplantation. The Electronic Health Record will offer people a convenient vehicle in future for recording their wishes as to what should happen to their body after death. Where an adult does not wish any part of his or her body to be used after death for transplantation, the most effective way of ensuring that those wishes are respected is to make them known to their GP, since transplant co-ordinators will contact the GP if there is any possibility of the person becoming an organ donor after death. Wishes can be conveyed either verbally, during a consultation, or by the person writing to their GP setting out their objections and asking for the letter to be added to their medical record. GPs should include a

note of any such objections in the emergency care summary which they provide for use out-of-hours.

14. One of the most significant changes in the new legislation relates to the role of the donor's nearest relatives. At present, organ donation only goes ahead if that is the wish of the relatives. This can lead to vetoing of deceased's wishes, as recent research by UKT shows that relatives refuse to agree to donation in 41% of cases (*Potential for organ donation in the United Kingdom: audit of intensive care records* BMJ, 13 May 2006, vol. 332 No. 7550, pages 1124-7). The main principle underpinning the new legislation is that a person's own wishes should be acted on. Nearest relatives will still need to be approached to find out if there are any medical reasons why transplantation should not go ahead, but where the wishes of the deceased adult or child aged 12 or over at the time of death are clear, it would be contrary to the terms of the 2006 Act to seek authorisation from the nearest relative or person with parental rights and responsibilities for the child, as the deceased's wishes in these cases are all that are needed to allow the removal of body parts to proceed lawfully.

15. Where the deceased left no formal wishes, the nearest relative (in the case of an adult) or a person with parental rights and responsibilities (in the case of a child who dies aged 12 or over) will be asked to consider giving authorisation on the basis of what they believe the deceased's wishes would have been. The 'nearest relative' hierarchy set out in section 50 of the 2006 Act aims to identify the person closest to the deceased in life and therefore most likely to be able to express the deceased's wishes, whether as a result of a direct discussion on the subject or otherwise.

16. Where a child dies under 12 years of age, authorisation would fall to be given by a person with parental rights and responsibilities. The 2006 Act makes it lawful to proceed on the basis of authorisation from one person with parental rights and responsibilities. That approach is consistent with the general provisions of the Children (Scotland) Act 1995 in relation to parental consent for medical treatment. The Act excludes a local authority which has parental rights and responsibilities from giving authorisation.

17. There may be cases where there are no surviving parents, in which case, in seeking authorisation, it would be necessary to discover whether the parents had appointed guardians under section 7 of the Children (Scotland) Act 1995. If such an appointment had not been made, and there is therefore no-one with parental rights and responsibilities, the nearest relative hierarchy does not apply, and transplantation would be unable to take place since there was no-one able to give the necessary authorisation.

18. The nearest relative or person with parental rights and responsibilities cannot withdraw authorisation for transplantation once it has been given, because of the potential risks a last-minute withdrawal could pose to the recipients of body parts. Authorisation for any of the other purposes set out in paragraph 10 can be withdrawn at any time, but this must be done in writing so that there is a clear record of the decision. This is especially important given that it is an offence to remove parts of a body after death unless there is clear authorisation to do so.

19. These authorisation arrangements will need to be reflected in new forms which the donor and tissue transplant co-ordinators should use in place of the present 'lack of objection' forms.

20. The Human Tissue (Removal of Body Parts by an Authorised Person) (Scotland) Regulations 2006 are being made under section 11 of the Act. These allow someone other than a registered medical practitioner to retrieve body parts from a deceased person, primarily for the purposes of transplantation, provided the registered medical practitioner authorising the retrieval is satisfied that the person undertaking the retrieval is competent to do so. These arrangements will apply to tissue only. The Director of Tissue Services, SNBTS, intends to train staff so that they can retrieve tissue such as tendons and bone, if possible in conjunction with the Scottish Organ Retrieval Team.

21. The storage etc of tissue for human application is now governed by the EU Directive on the Safety of Tissue and Cells, which came into effect on 6 April 2006, as indicated in the letter from Dr Aileen Keel, Deputy CMO, dated 1 March 2006. The Scottish Ministers and the Human Tissue Authority have agreed that the HTA will act as the Competent Authority for Scotland under the Directive, in order to preserve the UK-wide system of accreditation operated at present by the Medicines and Healthcare Products Regulatory Authority (MHRA). Regulations under the European Communities Act 1972, setting out the detailed requirements for Scotland, are in the process of being drafted, and the Executive intends to consult on the feasibility of having one set of Regulations covering the whole of the UK to promote consistency of approach.

Transplantation from living donors

22. The 2006 Act continues the approach in current legislation (the Human Organ Transplants Act 1989 and associated Regulations) and in the Human Tissue Act 2004 that the removal of organs, parts of organs or tissue from the body of a living person for use in transplantation constitutes an offence. Section 17 of the 2006 Act provides, however, that Regulations can be made to waive the offence provisions, if certain conditions are met. The detailed conditions are set out in the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006. The main requirements are that the donor should have authorised the removal and use for transplantation, has not been subject to coercion, and that no reward has been or is to be given in contravention of the prohibition on commercial dealings in parts of a human body for transplantation, as set out in section 20 of the Act.

23. At present, the scrutiny of cases of living donation is confined to those where the donor and recipient are unrelated, and that scrutiny is undertaken for Scotland by the Unrelated Living Transplants Regulatory Authority (ULTRA). ULTRA will cease to consider new applications with effect from midnight on 31 August 2006, but will continue in existence until every application made immediately before that date has completed all its stages. Scrutiny of living donation under the 2006 and 2004 Acts will be inherited by the Human Tissue Authority (HTA), in order to preserve the present UK-wide approach. It will commence this function on 1 September 2006 and will scrutinise related as well as unrelated cases, and applications involving parts of organs as well as whole organs, to reflect developments such as those which enable living people to donate of parts of livers and parts of lungs.

24. The Executive and the HTA have also agreed that in order to promote consistency across the UK, the arrangements for living donation set out in the Authority's Codes of Practice on Donation of Organs and Tissue and Donation of allogeneic bone marrow and peripheral blood stem cells (PBSC) will apply to Scotland. The 2006 Act does not cover the donation of tissue by living adults who have the capacity to make decisions in such cases, but

these cases will be subject to the arrangements set out in the HTA's Codes of Practice. The text of the Authority's Codes can be found on the HTA's website (www.hta.gov.uk).

25. The HTA is taking the opportunity offered by the new legislation to introduce new types of living organ donation: paired/pooled and non-directed. 'Paired' donation is where a close relation, friend or partner is fit and able to donate an organ but is not well-matched to the potential recipient, but that couple can be matched to others in a similar situation, so that both people in need of a transplant receive a well-matched organ. 'Pooled' donation is the extension of such an arrangement beyond 2 couples. 'Non-directed' donation is where a person donates organs, tissue or cells to a recipient who is unknown to them personally. These new types of donation will be available in Scotland as well, and work is going forward under the auspices of the Scottish Transplant Group, in association with the HTA and UKT, to develop the practical arrangements which will apply from 1 September 2006.

26. An increase in the volume of living donation was recognised at least as long ago as the publication of the report of the Acute Services Review (June 1996), as having a key part to play in tackling the shortage of organs, especially kidneys. In view of the expected increase in the number of cases of living donation, Boards are reminded of the terms of HDL (2004)51 of 14 December 2004 which sets out details of reimbursement of living donors. It is essential that arrangements should have been agreed in advance with the recipient's Board of residence.

27. In relation to children, by which is meant in this context those who have not reached the age of 16, and to adults with incapacity, only 2 forms of donation are open under the 2006 Act. One is the donation of regenerative tissue, which is defined in section 17(10) as 'tissue which is able to be replaced in the body of a living person by natural processes if the tissue is injured or removed'. 'Tissue' itself is defined in section 60(1) as including skin and bone marrow. It will therefore be possible under the 2006 Act for children and adults with incapacity to donate tissue such as bone marrow, peripheral blood stem cells (PBSC) and skin. These donations will be subject to scrutiny by the HTA, and decisions will be made on behalf of the Scottish Ministers by the Authority.

28. The other type of donation available to children and adults with incapacity is of an organ or part of an organ as part of a domino organ transplant operation, a procedure which is defined in section 17(10) of the Act.

29. Details of the arrangements which apply to donation by adults with incapacity and children are set out in Parts 3 and 4 of the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006. In general, the Human Tissue Authority, on behalf of the Scottish Ministers, must be satisfied that the donor is an adult with incapacity or a child, that the organ is being removed as part of a domino transplant operation or that the tissue being removed is regenerative tissue, that there is no unwillingness on the part of the donor, that information has been given to the donor and that there is no evidence of reward. The donor will be interviewed in all cases, and where it is practicable to do so, the adult's proxy or someone with parental rights and responsibilities for the child will also be interviewed to ascertain their views as to the adult's or child's past wishes and feelings on the issue of donation.

Other provisions relating to transplantation

30. Section 19 of the 2006 Act allows the Scottish Ministers to make Regulations dealing with the provision of information and the maintenance of records relating to transplantation and the other purposes set out in section 3(1) of the Act. The detailed requirements, which carry forward existing provisions under the 1989 Act and associated Regulations, are set out in the Human Tissue (Scotland) Act 2006 (Maintenance of Records and Supply of Information Regarding the Removal and Use of Body Parts) Regulations 2006. They relate to organs and parts of organs, and place record-keeping requirements on registered medical practitioners who remove a body part for transplantation and on anyone who receives a body part for research, education, training or audit purposes. A registered medical practitioner who receives a body part for transplantation is required to provide both the UKT Division of NHS Blood and Transplant and their NHS Board with certain information. This approach will allow the present arrangements for audit of transplantation activity across the whole of the UK to continue. The requirements of the Information Regulations will be reflected in the forthcoming HDL on the maintenance of medical records.

31. Where part of the body of a deceased person could be used for transplantation, section 13 of the 2006 Act allows the managers of certain premises to take steps to preserve the part of the body for that purpose. 'Managers' is not defined and local arrangements will need to be put in place determining who can take decisions in these cases. Only the minimum steps necessary can be taken, and the least invasive procedure must be used. The section applies to NHS hospitals and premises in which a registered independent health care service is provided. A manager's authority to preserve the body part ceases once it is clear that authorisation is not going to be given for transplantation. The body itself can be moved to other premises only where it is clear that authorisation for transplantation exists.

HOSPITAL POST-MORTEM EXAMINATIONS

32. Part 2 of the 2006 Act deals with post-mortem examinations other than those instructed by the Procurator Fiscal. These are commonly known as 'hospital' post-mortem examinations. The provisions in the Act on this subject represent the fulfilment of a commitment given by the Executive to the families distressed by the disclosures of past practice regarding organ retention that the law (the Human Tissue Act 1961) would be changed to make sure that never again would it be possible for a hospital post-mortem examination to be undertaken, or organs and tissue retained from it, without proper knowledge or permission. The Executive's intention is that the new legislation, in conjunction with the hospital post-mortem examination standards published by NHS Quality Improvement Scotland in 2002 and reported on in 2005, should promote confidence in the hospital post-mortem examination system on the part of both families and hospital staff.

33. Section 23 of the Act sets out the purposes for which a post-mortem examination may be undertaken:

- 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); and
- Audit, education, training or research.

These purposes clearly emphasise the role of the post-mortem examination as part of the continuum of care provided by the NHS, which extends beyond the death of the individual, as well as the benefits which can accrue to the community more generally.

34. Section 28(5) specifies the parts of the body which may be removed at post-mortem examination and retained for the purposes set out in section 23. These are: an organ; tissue sample; blood, or any material derived from blood; and other body fluid. Section 60 of the 2006 Act indicates that ‘tissue sample’ includes any derivative of skin, which is understood as including hair and nails.

35. The distinction in the Act between tissue samples and organs reflects the different emotional significance these can have. Tissue samples automatically become part of the deceased’s medical record, as do any tissue samples taken from organs removed and retained at the examination.

36. The carrying out of a post-mortem examination, and the retention of tissues and organs thereafter, depend on proper authorisation having been obtained. The principle of authorisation is the same as set out in relation to transplantation, with the same three-fold categorisation into: adults; children who die aged 12 or over and children who die aged less than 12. Broadly the same arrangements apply as described in paragraphs 9 and 10. A key difference is, however, that an adult or a child who dies aged 12 or over can, during their lifetime, nominate one or more representatives to make decisions about post-mortem examinations. Where an adult or child who died aged 12 or over left no wishes, no nominees and has no nearest relative or person with parental rights or responsibilities, there will be no one who can give authorisation, and it will not be lawful to perform a hospital post-mortem examination in these cases.

37. Self-authorisation in the context of post-mortem examinations is not uncommon in groups of patients with neurological conditions such as Parkinson’s Disease and Motor Neurone Disease, whose spouse or partner will also often agree to bequeath their own brain for control purposes. The Executive does not intend to produce a form for use by those who wish to give self-authorisation, but is exploring the Electronic Health Record (EHR) as a vehicle for recording such wishes. Self-authorisations given by an adult can either be in writing and signed by the adult, or expressed verbally in the presence of 2 witnesses. There are specific arrangements where the person is blind or unable to write.

38. The Executive recognises that there are those who wish to register during their lifetime an objection to a post-mortem examination being carried out on them. Such wishes should be respected, in the same way as should wishes in favour of a post-mortem examination. The best vehicle for capturing objections is, as explained in paragraph 13, a letter to the person’s GP. The EHR should also provide a vehicle in the future.

39. Where authorisation is given by a nominated representative, nearest relative or person with parental rights and responsibilities, the standard authorisation form should be used, in order to address one of the main concerns about past practice: the variation in approaches across Scotland. In line with the provisions of the Act, there are 3 such forms: one for adults, one for children who died aged 12 or over, and one for children who dies aged less than 12 years. The mandatory nature of these forms is made clear in the NHS Quality Improvement Scotland clinical standards for hospital post-mortem examinations.

40. These forms, and the accompanying Information Leaflets, were the subject of a formal consultation by the Executive, launched in April 2006, in order to ensure that any examples of good practice locally could be incorporated in the definitive version of the forms

and leaflets. An initial supply of forms and leaflets is being provided separately to all hospitals by the Executive, and the Executive wishes to monitor closely their use and effectiveness. Ministers have the power to specify the content of these forms in Regulations which can be made under section 52 of the 2006 Act, and the Executive may decide in the light of experience of using the forms, to incorporate them in Regulations. The Executive also intends to work with NHS Education for Scotland and others to develop training programmes for those members of staff who will have to work through the forms with bereaved families.

41. In terms of the 2006 Act, a post-mortem examination can go ahead if the deceased person, a nominated representative, a nearest relative or a person with parental rights and responsibilities, as the case may be, has authorised it. There may be unusual circumstances in which relatives disagree strongly over whether a post-mortem examination should be carried out. The legislation presumes that the wishes expressed by the deceased person should be fulfilled, but where any disagreement cannot be resolved through discussion, hospitals will need to establish a procedure for deciding whether the post-mortem examination can proceed.

42. The authorisation forms include a tick box indicating agreement to the testing for genetic diseases of any material retained from the post-mortem examination. This is intended to avert the possibility of any criminal offence being committed under the provisions of section 45 of and Schedule 4 to the 2004 Act. These relate to the non-consensual analysis of DNA, and extend to Scotland.

43. The offence provisions in the 2006 Act address one of the key criticisms of the previous system: the lack of legal sanctions. They are included in order to underline the importance attached to authorisation and to ensuring that the exact terms of authorisation are respected. Section 49 provides that any conditions attached to authorisation should be adhered to where reasonably practicable, and this is provided for in Section 4 of the standard authorisation forms.

44. Section 36 of the 2006 Act provides that an organ or tissue sample held in an existing archive or collection before 1 September 2006 as the result of a hospital post-mortem examination can continue to be kept and used for any of the purposes of audit, education, training or research. There is therefore no need to seek authorisation for the retention of the material for these purposes. This provision incorporates into the legislation the essence of the 5-year agreement reached by the Review Group on Retention of Organs at Post-Mortem and the family support groups with which it was dealing. Notification of these arrangements was contained in a letter of 12 April 2002 from the Deputy CMO. A key feature was that research was possible on this material from 6 months into the 5-year period provided the research was significant, did not involve the use of all the material and had REC approval.

45. The arrangements reflected the value for medicine and for society which this material has, and the assumption is that such material should be held in collections so long as its value continues. Hospitals and other institutions will wish to carry out an assessment of this material. Where it would be unlikely to be put to use if kept, it would be more in line with what is known of families' feelings to arrange for its disposal. That should be done as respectfully as possible, bearing in mind the additional options made available by the Cremation (Scotland) Amendments Regulations 2003 (SSI 2003 No. 301), which allow for the cremation of parts of a body retained from a post-mortem examination.

Tissue Sample or Organs no longer required for Procurator Fiscal Purposes

46. The Review Group on Retention of Organs at Post-Mortem recognised the importance of ensuring the continued availability for diagnostic and other purposes of organs and tissue retained from a post-mortem examination carried out on the instructions of the Procurator Fiscal, but wanted the new legislation to be clear about the basis of that retention. Part 3 of the 2006 Act addresses this concern.

47. In order to trigger the provisions of Part 3, the Procurator Fiscal must notify the establishment where the post-mortem examination took place that the organ or tissue is no longer needed for the purposes of the Fiscal's functions. The Executive (Health Department, Justice Department and Crown Office and Procurator Fiscal Service) is working with the Scottish Regional Council of the Royal College of Pathologists on the detailed procedures required to implement this process of notification. The broad requirements are set out in the Human Tissue (Specification of Posts) (Scotland) Order 2006, which provides that where the examination was carried out in a university, notification should be sent to the head of forensic pathology. For any other establishment, including an NHS hospital, the Order provides that notification should be sent to the manager of the establishment. In practical terms, the notification will need to be passed to the pathologist who carried out the examination instructed by the Fiscal, or his or her successor.

48. Section 39 of the 2006 Act provides that once the necessary notice has been received from the Fiscal, the 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); and
- audit.

49. The tissue blocks and slides can also be used for the purposes of education, training or research, but only if specific authorisation has been given. Although the Act does not prescribe that research involving these tissue blocks and slides should require Research Ethics Committee approval, those responsible for the research project would be expected to obtain such approval.

50. Where an organ is no longer required for the Fiscal's purposes, there must be specific authorisation for its retention, since an organ does not automatically become part of the deceased's medical record. Where the organ is to be used for research, the research must be approved in writing by such person(s) or group(s) as the Scottish Ministers may specify by order under section 40(2)(c). The Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specification of Persons) (Scotland) Order 2006 provides that approval must be given by a Research Ethics Committee.

51. The system of authorisation is generally similar to that under Parts 1 and 2 of the 2006 Act, falling into 3 categories: self-authorisation by an adult or by a child who died aged 12 or over; authorisation by the adult's nearest relative, which for the purposes of this Part of the Act includes a person who had a long-standing professional relationship with the adult (see

section 50(2)); authorisation by a person with parental rights and responsibilities in the case of a child who died aged less than 12 years of age, or a child who died aged 12 years or over but who did not leave any authorisation.

52. The Executive expects that the main reason for seeking authorisation in such cases will be in relation to research, and those pursuing a specific research project will generally be responsible for ensuring that authorisation is obtained in accordance with the terms of Part 3 of the 2006 Act. It is not intended to prescribe a specific form for these types of authorisation, thereby allowing those responsible for the project to devise a form suited to the needs of that project. The Executive will, however, keep under review the need to prescribe a standard form under section 52(b), in the light of experience of the use made of the powers under Part 3 of the 2006 Act.

53. Meanwhile, the Crown Office and Procurator Fiscal Service is adapting the leaflets it provides to families about Fiscal post-mortem examinations in order to explain to families the position under Part 3 the 2006 Act regarding tissue blocks and slides, and the options open to them of authorising wider uses of the tissue blocks and slides and whole organs. The provision in section 39(b) on research is understood as relating to the use of samples from a particular case, usually in conjunction with samples from a number of similar cases, to discover new information about a disease. This will probably not be of immediate or obvious benefit to the relatives of the deceased person. Section 39(a)(iii), by contrast, relates to conducting tests on stored material from a specific case when new questions or information come to light which suggest that it is important to explore the stored blocks further. This further investigation would be of much more direct relevance to the family.

54. Part 3 also contains important provisions about material in existing collections which was derived from forensic post-mortem examinations which took place before the Act comes into operation. Section 47 allows tissue blocks and slides acquired from a post-mortem examination instructed by the Fiscal prior to 1 September 2006 to continue to be used for the purposes of education, training and research without the need to obtain authorisation in terms of the 2006 Act. This provision applies whether or not the blocks and slides are also being retained and used for the purposes of the functions of the fiscal. Where the blocks and slides are being used in research, it is assumed that the project will have received Research Ethics Committee approval, in keeping with the arrangements referred to in paragraph 44.

55. As with the material in existing collections retained from a hospital post-mortem examination, which is dealt with by section 36 of the Act, the provisions of Part 3 of the Act are based on the agreement reached between the Review Group and the family support groups (see paragraph 42). They therefore replace the arrangements for the 5 year period which began on 18 April 2002. Those responsible for collections containing such material will wish to assure themselves that the material is of enduring value in respect of the purpose for which it has been retained. Where that value has been lost, and no further use is likely to be made of the material, it should be disposed of as respectfully as possible, bearing in mind the opportunities arising as a result of the amended Cremation Regulations (see paragraph 45).

56. Section 48 provides that organs acquired from a post-mortem examination instructed by the Fiscal prior to 1 September 2006 can continue to be used for the purposes of education, training and existing Research Ethics Committee-approved research without the need to obtain authorisation in terms of the 2006 Act or any further approval. This provision

applies whether or not the organs are also being retained and used for the purposes of the functions of the fiscal. Where there is a wish to use the organs for a research project starting after 1 September 2006, however, approval needs to be obtained from such person(s) or group(s) as the Scottish Ministers may specify in an order under section 48. The Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specification of Persons) (Scotland) Order 2006 specifies Research Ethics Committees as the bodies which should approve future research on material acquired before 1 September 2006.

AMENDMENTS TO THE ANATOMY ACT 1984

57. The key difference for NHSScotland concerns authorisation for the donation of a body. Under the 1984 Act as originally drafted, a person could give verbal consent to donate his or her body during the final illness. This is no longer permissible under the 1984 Act as amended by the 2006 Act. Authorisation to leave the body to medical science must now be in writing, and, in cases of deceased adults, must be countersigned by one witness. If the deceased person is a child aged 12 years or over, the authorisation must be witnessed by 2 adults, who must also confirm that the child understood the effect of the authorisation and was not acting under undue influence. If the person giving authorisation is unable to write, the authorisation must be signed by an adult on behalf of that person, and witnessed by a second adult, and both must confirm that the person expressed an intention to give authorisation and requested the signatory to sign on his or her behalf. It is hoped that a standard authorisation form will be developed for use throughout Scotland.