

HUMAN TISSUE (SCOTLAND) BILL

EXPLANATORY NOTES (AND OTHER ACCOMPANYING DOCUMENTS)

CONTENTS

1. As required under Rule 9.3 of the Parliament's Standing Orders, the following documents are published to accompany the Human Tissue (Scotland) Bill introduced in the Scottish Parliament on 3 June 2005:

- Explanatory Notes;
- a Financial Memorandum;
- an Executive Statement on legislative competence; and
- the Presiding Officer's Statement on legislative competence.

A Policy Memorandum is printed separately as SP Bill 42-PM.

EXPLANATORY NOTES

INTRODUCTION

2. These Explanatory Notes have been prepared by the Executive in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by the Parliament.

3. The Notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a section or schedule, or a part of a section or schedule, does not seem to require any explanation or comment, none is given.

THE BILL – AN OVERVIEW

4. The main provisions of the Bill are as follows:

Part 1– Transplantation etc.

- sets out the Scottish Ministers’ duties as respects transplantation, makes provision for the authorisation of the use of parts of the body of a deceased person for purposes of transplantation, research, etc, contains restrictions on transplants involving living donors, and prohibits commercial dealings in human body parts for transplantation;

Part 2 – Post-mortem examinations

- makes provision for the authorisation of hospital post-mortem examinations by an adult or mature child while still alive, or, failing such authorisation, by a nominee of the person or by his or her nearest relative, and, for children, authorisation by a person with parental rights and responsibilities;

Part 3 – Tissue sample or organs no longer required for Procurator Fiscal Purposes

- provides for tissue samples no longer required for the Fiscal’s purposes to be retained as part of the deceased’s medical record and used without authorisation for diagnostic and audit purposes, and for such tissue samples and organs no longer required for the Fiscal’s purposes to be used, with authorisation, for education, training or research;

Part 4 – Supplementary provision to Parts 1 to 3

- defines ‘nearest relative’ and makes provision about witnessing of authorisations and related matters

Part 5 – Amendment of the Anatomy Act 1984

- makes changes to provisions which govern the use of cadavers and body parts for the purposes of anatomical examination, the principal purpose being: to allow for the practice of surgical reconstruction to be carried out on bodies and body parts and also the practice of removing whole organs and parts of organs by healthcare professionals; prevent any unlicensed exhibition of bodies and body parts in public exhibitions under the guise of education or art, and enable the post of HM Inspector of Anatomy for Scotland to continue following changes in England and Wales.

Part 6 – Miscellaneous

- makes provision to allow the Scottish Ministers to arrange with a public authority anywhere in the UK to assist them with certain of their functions under the Bill, and gives the Scottish Ministers power by regulations to amend the Act in order to give effect to Community obligations relating to material consisting of human cells.

Part 7 – General

- contains ancillary provisions and provisions relating to interpretation, repeals, commencement, etc

PART 1: TRANSPLANTATION ETC.

Section 1 – Duties of the Scottish Ministers as respects transplantation, donation of body parts etc.

5. Section 1 sets out the Scottish Ministers' duties with respect to promoting, developing and supporting transplantation programmes and the donation of parts of the human body for transplantation, including a duty to promote the taking of any necessary measures relating to the quality and safety, storage and use of body parts donated for transplantation.

Section 2 – Assistance and support

6. Section 2 allows the Scottish Ministers to provide assistance and support to those providing, or proposing to provide, a service relating to transplantation. 'Assistance' is defined to include financial assistance.

Section 3 – Use of body of deceased person for transplantation, research etc

7. Section 3 provides that a part of a deceased person's body can be removed after that person's death and used for all or any of the purposes of transplantation, research, education and training or audit. The removal of the body part must have been authorised appropriately, in terms of section 6, 7, 9, 10 or 11, and must be undertaken either by a registered medical practitioner or by someone who has been authorised to do so by a registered medical practitioner (section 12(1) and (2)). The other requirements of section 12 must also have been satisfied.

Section 4 – Disapplication of sections 3, 6 to 12 and 14 in certain circumstances

8. Section 4 makes clear that none of the relevant provisions of this Part apply in certain circumstances. They do not affect in any way anything done for the purposes of the functions or under the authority of the procurator fiscal. They do not apply in relation to the removal of a body part during a post mortem examination or the subsequent retention and use of the part. Nor do they apply in relation to the retention of tissue samples or organs removed from a body during an examination carried out for the purposes of, or under the authority, of the procurator fiscal before the coming into force of the relevant provisions in the legislation relating to authorisation.

Section 5 – Consent by procurator fiscal to removal of part of body

9. This section is based on the equivalent provision in section 1(5) of the Human Tissue Act 1961 (c.54) and provides that where a person knows, or has reason to believe, that an examination

of the body may be required for the purposes of the procurator fiscal, the person may not remove a body part, or authorise anyone else to remove a body part, for the purposes of section 3(1) unless the fiscal consents. The fiscal's consent can be given verbally, provided it is confirmed in writing as soon as reasonably practicable.

Section 6 – Authorisation: adult

10. Subsection (1) makes clear the adult's power to authorise the removal and use of a part of the adult's own body after death for purposes of transplantation or any of the other purposes specified in section 3(1) (research, education or training or audit). Subsection (2) provides that such authorisation may be in writing, or can be given verbally. If expressed verbally, this must be done in the presence of 2 witnesses. Authorisation can be withdrawn, but the withdrawal must be in writing.

Section 7 – Authorisation by adult's nearest relative

11. Section 7(1) provides that where no authorisation by the adult for the removal and use of body parts for transplantation is in force immediately before the adult's death, the adult's nearest relative can authorise the removal and use of any body part for one or more of the purposes set out in section 3(1), provided the terms of section 7(4) are satisfied.

12. Section 7(2) provides that if there is in force immediately before an adult's death authorisation of the removal and use of body parts for transplantation, but that authorisation does not expressly include removal and use of the body parts for education or training, research or audit, the nearest relative can authorise the removal and use for one or more of those purposes, provided the terms of section 7(4) are satisfied.

13. Section 7(3) provides that if there is in force immediately before an adult's death authorisation of the removal and use of a particular body part for transplantation and the authorisation does not expressly include removal and use of another particular part, the nearest relative can authorise the removal and use of the other particular part for one or more of the purposes of education and training, research and audit, provided the terms of section 7(4) are satisfied.

14. Section 7(4)(a) provides that the nearest relative may not give authorisation under section 7(1) if he or she has actual knowledge that the adult was unwilling for any part of the adult's body, or the part in question, to be used for transplantation. Section 7(4)(b) provides that the nearest relative may not give authorisation under section 7(2) if he or she has actual knowledge that the adult was unwilling for the body part to be used for the purpose in question. Section 7(4)(c) provides that the nearest relative may not give authorisation under section 7(3) if he or she has actual knowledge that the adult was unwilling for any other part of the adult's body, or the other particular part in question, to be used for transplantation.

15. Section 7(5) provides that 'unwillingness' should not be implied simply by the fact that the adult had not provided authorisation as respects the particular purpose, use or part.

16. Section 7(6) provides that authorisation by the nearest relative must be in writing and signed, and may be withdrawn in writing and signed by the nearest relative.

Section 8 – Existing written request: adult

17. This section provides that written requests made by the adult before the coming into operation of the provisions in sections 3 and 6 should count as if they were authorisations made in terms of those sections. This ensures that all current decisions by adults to carry a donor card or register on the NHS organ donor register will count as authorisations in terms of the new legislation.

Section 9 – Authorisation: child 12 years of age or over

18. Subsection (1) allows a child who is 12 years of age or older to authorise the removal and use of a part of their body after the child's death for one or more of the purposes of transplantation, education or training, research or audit. Subsection (2) provides that such authorisation must be in writing, and that the authorisation may be withdrawn in writing.

Section 10 – Authorisation as respects child who dies 12 years of age or over by person with parental rights and responsibilities

19. Section 10 provides that if there is in force immediately before the death of a child who died 12 years of age or over no authorisation by the child of the removal and use of any part of the child's body for transplantation, a person who immediately before the death of the child had parental rights and responsibilities in relation to the child may authorise the removal and use of any part for one or more of the purposes of transplantation, education or training, research or audit.

20. Sub-sections (2) to (5) repeat, in the context of those having parental rights and responsibilities in relation to a child 12 years or older, the provisions relating to authorisation by an adult's nearest relative, as described in paragraphs 12-15 above.

21. Subsection (6) provides that authorisation by virtue of section 10 must be in writing and signed by the person giving the authorisation, and may be withdrawn in writing and signed by the person.

Section 11 – Authorisation as respects a child who dies under 12 years of age

22. Section 11(1) provides that where a child dies under 12 years of age, authorisation of the removal and use of a part of the child's body for one or more of the purposes of transplantation, education or training, research or audit can be given by a person who immediately before the death of the child had parental rights and responsibilities in relation to the child. Section 11(2) provides that such authorisation must be in writing and signed by the person who provides the authorisation, and can be withdrawn in writing and signed by the person.

Section 12 – Removal of part of body of deceased person: further requirements

23. Section 12(1) provides that removal of a body part for transplantation, or for any of the other purposes set out in section 3(1), must be undertaken by a registered medical practitioner or someone authorised to do so in accordance with regulations made by the Scottish Ministers. Section 12(2) specifies that such regulations can in particular provide for a registered medical practitioner to authorise the removal by a non-practitioner. The intention is to make such regulations so that tissue

(as opposed to solid organs) could be retrieved by someone who has been trained to do so but may not be a registered medical practitioner.

24. Subsection (3) provides that the body part may not be removed unless the person who proposes to undertake the removal meets the requirements of section 12(4). In addition, a registered medical practitioner who proposes to authorise another person to undertake the removal must also meet those requirements.

25. The requirements in subsection (4) are that the person undertaking the removal (and where a registered medical practitioner proposes to authorise another person to undertake it, that practitioner) must be satisfied, either by personal examination, or from the personal examination by another registered medical practitioner, that life is extinct; that any necessary consent of the procurator fiscal under section 5(1) has been provided; and that the removal is authorised in accordance with the relevant section of the Act.

26. Subsection (5) provides that the person undertaking the removal (and where a registered medical practitioner proposes to authorise another person to undertake it, that practitioner) is entitled to be satisfied that the relevant authorisation is in place in specified circumstances, as follows: The authorisation forms used by the transplant co-ordinators will be adapted to make sure they reflect each of the requirements in relation to written authorisations which are set out in this subsection.

27. Paragraphs (a), (b), (d), (e), (f), (g), (h), (i), (j) and (k) all relate to written authorisations under various provisions in Part 1 of the Bill. These paragraphs reflect the fact that the practitioner and any other person undertaking the removal will need to know that it is acceptable for them to proceed on the basis of the proper authorisation, thereby avoiding any invocation of the provisions of section 14, which provide that an offence is committed if removal and use of the body part is not authorised by the relevant provision in Part 1.

28. Paragraph (c) relates to verbal authorisation by an adult under section 6(1). In such cases, there requires to be what that person undertaking the removal (or the practitioner, as the case may be) considers to be an appropriate record of the authorisation by the adult. The person or practitioner is also entitled to be satisfied that the removal is authorised in accordance with section 6(1) if the verbal authorisation bears from the record to be as respects the deceased adult, to authorise removal of the part for the purpose in question and to have been expressed verbally in the presence of two adult witnesses. Again, this provision reflects the fact that the practitioner and any other person undertaking the removal will need to know when it is acceptable for them to proceed, in light of the offence provisions. What is or is not an appropriate record of the verbal authorisation is a matter to be determined by the practitioner and any other person undertaking the removal. "Appropriate record" is not defined for the purposes of this provision, to avoid being too prescriptive and thereby allow for advancing technology over time in relation to recording devices.

Section 13 – Preservation for transplantation

29. This section provides for the maintenance of a dead body in a condition that would allow transplantation of parts of the body to take place. The provision is intended to allow steps to be taken to preserve the function of a body part until it can be established whether there is authorisation for the use of the body part for transplantation. The section also provides that the

minimum steps necessary should be taken to preserve the body, and the least invasive procedure used. Preservation must be stopped as soon as it becomes clear that no authorisation will be given for transplantation.

30. Subsections (4) and (5) define the premises where such procedures may be carried out.

Section 14 – Offences: removal or use of part of body of deceased person for transplantation, research, etc

31. Section 14(1) provides that it is an offence to remove or use a body part for the purposes of transplantation or any of the other purposes set out in section 3(1) without having the necessary authorisation, or if the removal is undertaken by someone who is not a registered medical practitioner, or a person whom such a practitioner has authorised to undertake the removal in terms of regulations under section 12(1), or if the person undertaking the removal has not satisfied himself that life is extinct in terms of section 12(4)(a).

32. Subsection (2) provides that it is a defence for a person charged with an offence under subsection (1) to show that at the time of carrying out the activity, the person reasonably believed that it had been authorised in accordance with the relevant section of the Act or that the requirements of section 12(1) or (4) (a) or (c) had been satisfied as respects the part of the body (requirements as to who may carry out the removal or authorise it and as to being satisfied that the body is a dead body).

33. Subsection (3) sets out the penalties attaching to an offence under section 14(1).

Section 15 – Restrictions on transplants involving live donor

34. This section broadly carries forward the arrangements at present under section 2 of the Human Organ Transplants Act 1989 (c.31), which set up a system of scrutiny of transplantation of organs from living donors. The new provisions, which equate to section 33 of the Human Tissue Act 2004 (c.30), will apply not just to whole organs but also to parts of organs, to take account of developments such as the possibility of transplanting parts of the liver of a live donor. The system of scrutiny will also be extended to cover all transplants from living donors, whether they are related or unrelated.

35. Subsection (1) makes it an offence to remove an organ, part of an organ or tissue from a living adult or child with the intention that it be used for transplantation unless the exceptions provided for in subsections (3) and (5) apply. ('Adult' means a person 16 years of age or over and 'child' means a person under the age of 16 – section 54(1).) The offence is committed where the person who carries out the removal knows, or might reasonably be expected to know that the removal is made from a living adult or child. The offence also applies to the removal from a living child of any tissue other than tissue which is regenerative, by which is meant tissue which, after injury or removal, is replaced by the body of a living person by natural processes (subsection (7)). This exception is to allow in particular bone marrow to continue to be transplanted between children, although subject to the overall system of scrutiny. Subject to subsections (3) and (5), an offence is committed if a person does any of these things and at the time knows, or might reasonably be expected to know, that the removal is from a living adult or child.

36. Subsection (2) makes it an offence, subject to the provisions of subsections (3) and (5), to use for transplantation, an organ or part of an organ which has come from the body of a living adult, or an organ, part of an organ or non-regenerative tissue which has come from the body of a living child. Again the offence is committed if when the person does so he or she knows, or might reasonably be expected to know, that the organ, part or tissue has come from a living adult or child.

37. Subsection (3) gives the Scottish Ministers power by regulations to provide that no offence is committed under subsection (1)(b) (in relation to removal of an organ or part of an organ from the body of a living adult intending that it be used for transplantation) or under subsection (2)(b) (in relation to using for transplantation an organ or part of an organ which has come from the body of a living adult) where the requirements mentioned in subsection (3) are met. The requirements are that the Scottish Ministers must be satisfied that no reward has been or will be given in contravention of the provisions of section 17 (prohibition of commercial dealings in parts of a human body for transplantation) and that such other requirements as may be specified in the regulations are complied with. Where regulations provide for such an exception from the offence provisions in subsection (1)(b) or (2)(b), it is sufficient if the person reasonably believes that the exception applies (subsection (5)).

38. Subsection (4) provides that in making regulations under subsection (3) the Scottish Ministers must include a provision allowing for appeals against decisions relating to matters dealt with by the regulations.

39. 'Reward' is defined in subsection (7) as any description of financial or other material advantage, but excluding certain types of payment in money or money's worth. One type of payment excluded is payment for defraying or reimbursing any liability incurred by a third party in relation to removing, transporting, preparing, preserving or storing the organ, organ part or tissue for transplantation. This is particularly important in the context of bone marrow transplantation where there are registries which charge a fee for expenses associated with the procurement of bone marrow internationally.

40. Subsection (6) sets out the penalties attaching to an offence under section 15.

Section 16 – Records, information etc.: removal and use of parts of human bodies for transplantation etc.

41. This section carries forward the provisions of section 3 of the Human Organ Transplants Act 1989 (c.31), and parallels the provisions of section 34 of the Human Tissue Act 2004 (c.30).

42. Subsection (1) allows the Scottish Ministers to make regulations requiring the maintenance of records in connection with the removal, use and retention of body parts for transplantation purposes, or any of the other purposes referred to in section 3(1), and for the provision of information to the Scottish Ministers, or such authority as may be specified in the regulations, with respect to such matters.

43. Under subsection (2), the Scottish Ministers must keep a record of the information provided to them in terms of regulations made under subsection (1).

44. Under subsection (3), any authority specified in the regulations must keep a record of the information provided to it in pursuance of the regulations.

45. Subsection (4) provides that failure to comply with regulations under subsection (1) without reasonable excuse, or knowingly or recklessly supplying false or misleading information, is an offence.

46. Subsection (5) sets out the penalties attaching to an offence under subsections 16(4)(a) or (b).

Section 17 – Prohibition of commercial dealings in parts of a human body for transplantation

47. This section broadly carries forward the provisions currently in section 1 of the Human Organ Transplants Act 1989 (c.31), and parallels the provisions of section 32 of the Human Tissue Act 2004 (c.30).

48. Subsection (1) provides that a person commits an offence if the person gives or receives a reward for the supply of, or for an offer to supply, any part of a human body for transplantation. It is also an offence to seek to find a person willing to supply for transplantation any part of a human body for reward, or to offer to supply any part of a human body for transplantation for reward, or to initiate or negotiate an arrangement involving the giving of a reward for the supply of, or for an offer to supply, any part of a human body for transplantation. It is also an offence to take part in the management or control of a body corporate or group of people whose activities consist of or include the initiation or negotiation of such arrangements.

49. Subsection (2) provides that it is also an offence if a person publishes or distributes an advert inviting people to supply, or offers to supply, any part of a human body for transplantation for reward. Similarly, this subsection also makes it an offence to indicate in an advertisement that the advertiser is willing to initiate or negotiate an arrangement involving the giving of a reward for the supply of, or an offer to supply, any part of a human body for transplantation, as set out in subsection (1)(d).

50. Subsection (3) allows the Scottish Ministers to exempt certain persons from the offence provisions by designating them as being able lawfully to engage in activities under sections (1) and (2). This is intended to preserve the existing position under which certain organisations, such as the registries mentioned in paragraph 39, assist with obtaining tissue for transplantation in particular on a not-for-profit basis.

51. Subsection (4) sets out the penalties attaching to an offence under section 17(1) and subsection (5) sets out the penalties attaching to an offence under sections 17(2).

52. Subsection (6) provides definitions of the terms “advertisement” and “reward” used in section 17.

Section 18 – Summary proceedings for offences under sections 15, 16(4) or 17(1) or (2)

53. This section provides that the time bar on summary proceedings in relation to any of these offences would come into operation 6 months after evidence sufficient to justify proceedings comes to the Lord Advocate's knowledge.

PART 2: POST-MORTEM EXAMINATIONS

Section 19 – Meaning of post-mortem examination for purposes of Act

54. This section provides a comprehensive definition of a post-mortem examination for the purposes of the Act, defining it in terms of the examination of the body of a deceased person and the purposes for which that examination is carried out.

Section 20 – Disapplication of sections 19 and 22 to 32 as respects procurator fiscal

55. This section provides that none of the relevant provisions of this Part affect in any way anything done for the purposes of the functions, or under the authority of, the procurator fiscal. The provisions of the Part apply therefore only in relation to post-mortem examinations as defined in section 19 (in practice referred to generally as "hospital post-mortems"), as opposed to examinations of dead bodies instructed by or carried out for the purposes of the procurator fiscal.

Section 21 – Consent by procurator fiscal to post-mortem examination

56. This section equates to the provision in section 1(5) of the Human Tissue Act 1961 (c.54) with regard to post-mortem examinations. Where the person proposing to undertake a post-mortem examination knows, or has reason to believe, that the fiscal's purposes may require an examination of the body, the post-mortem examination may not be carried out unless the consent of the fiscal has been obtained. The fiscal may give consent verbally, provided it is confirmed in writing as soon as is reasonably practicable.

Section 22 – Requirements for carrying out post-mortem examination

57. This section provides that a hospital post-mortem examination cannot be carried out unless it has been duly authorised and the further requirements in relation to post-mortem examination and removal and retention of organs under section 30 are satisfied.

Section 23 – Removal during examination and retention of organs and other parts of a body

58. Section 23(1) provides that where a post-mortem examination has been duly authorised, certain parts of the body of the deceased person may be removed from the body during examination for the purposes of the examination or for the purposes of audit, education, training or research; those parts may also be retained and used thereafter for any those purposes. Subsection (5) defines the parts of the body which can be removed during the examination or retained thereafter for any of the specified purposes. Subsection (6) provides that no other part of the body may be removed at post-mortem examination, and it follows therefore that no other part of the body could be retained as a result of a post-mortem examination. (These, and subsequent provisions relating to authorisation are based on the fact that authorisation of a hospital post-mortem examination

includes authorisation of the removal and retention of tissue samples as part of the deceased person's medical record.)

59. Subsection (2) provides that an organ may be removed during a post-mortem examination for the purposes of audit, education training or research if the removal is duly authorised for the purpose in question under the relevant sections of the Act. Similarly, an organ may be retained and used thereafter for any of these purposes only if the purpose in question has been duly authorised.

60. Subsection (3) provides that any part of the body of a deceased person (other than an organ) which is duly authorised to be removed during a post-mortem examination will form part of the medical records of the deceased person after its removal. Subsection (4) thereafter provides that where an organ has been removed in this manner, samples may, by virtue of that authorisation be taken from the organ and, if taken, will form part of the medical records of the deceased person.

Section 24 – Authorisation of post-mortem examination etc.: adult

61. Subsection (1) enables an adult to authorise a hospital post-mortem examination of his or her body after his or her death. An adult may also authorise the removal from their body during the post-mortem examination of an organ, and the retention and use of an organ for one or more of the purposes specified in section 23(2)(a) (audit, education, training or research).

62. Subsection (2) provides that such an authorisation under subsection (1) must be in writing, or it can be given verbally. If expressed verbally, this must be done in the presence of 2 witnesses. Subsection (3) further provides that a written authorisation may be withdrawn by the adult provided that it is withdrawn in writing and that a verbal authorisation may be withdrawn by the adult either in writing or verbally in the presence of 2 witnesses.

Section 25 – Authorisation of post-mortem examination etc by adult's nominee or nearest relative

63. Section 25(1) provides that an adult can nominate one or more people to authorise a post-mortem examination on the adult after the adult's death and the removal and retention and use of organs for one or more of the purposes specified in section 23(2)(a) (audit, education, training or research). Subsection (2) further provides that where on the adult's death there is neither an authorisation nor such a nomination of a representative in place, the nearest relative may authorise a post-mortem on the adult and the removal and retention of organs for one of the specified purposes.

64. Subsection (3) provides that where a nominated person is unable to give authorisation or there is insufficient time to contact that person the nomination must be disregarded and the nearest relative could be approached for authorisation.

65. Subsection (4) provides that authorisation by a nominated person must be in writing and signed and witnessed by one other person who has not been so nominated. Subsection (5) further provides that authorisation by a nearest relative must be in writing and signed and witnessed by one other person. Subsection (6) provides that in providing authorisation, a nominee or nearest relative must state, in relation to a post-mortem examination, that they have no actual knowledge that the adult was unwilling for a post-mortem examination to be carried out and, in relation to the removal

or retention and use of an organ after the examination, that they have no actual knowledge that the adult was unwilling for the activity in question to be carried out.

66. Subsections (7) and (8) provide that authorisation can be withdrawn by the nominated person or nearest relative in writing in the presence of one witness. In the case of a nominee withdrawing their authorisation in writing, the witness to that writing cannot be another nominee.

Section 26 – Authorisation of post-mortem examination etc.: child 12 years of age or over

67. Subsection (1) allows a child who is 12 years of age or older to authorise a post-mortem examination after the child's death and the removal from their body and retention and use thereafter of organs for one or more of the purposes specified in section 23(2)(a) (audit, education, training or research).

68. Subsection (2) provides that such authorisation must be in writing signed by the child and witnessed by 2 witnesses. It may be withdrawn by the child in writing signed by the child.

Section 27 – Authorisation of post-mortem examination etc as respects child 12 years of age or over by nominee or person with parental rights and parental responsibilities

69. Subsection (1) provides that a child 12 years of age or over can nominate one or more people to authorise a post-mortem examination on the child after the child's death and the removal, retention and use of organs for one or more of the purposes specified in section 23(2)(a) (audit, education, training or research). Subsection (2) further provides that where on the child's death there is neither an authorisation nor such a nomination by the child of a representative in place, a person who immediately before the death of the child had parental rights and responsibilities in relation to the child can give authorisation for a post-mortem on the child and the removal and retention of organs for one of the specified purposes.

70. Subsection (3) provides that where the child's nominee is unable to give authorisation or there is insufficient time to contact that person then the nomination must be disregarded and the nearest relative could be approached for authorisation.

71. Subsection (4) provides that authorisation by a child's nominee must be in writing, signed and witnessed by 2 witnesses who have not been so nominated. Subsection (5) further provides that where authorisation is given by a person with parental rights and responsibilities in relation to the child this must be in writing, signed and witnessed by 2 witnesses.

72. Subsection (6) provides that in providing authorisation the child's nominee or the person with parental rights and responsibilities in relation to the child must state, in relation to a post-mortem examination, that they have no actual knowledge that the child was unwilling for a post-mortem examination to be carried out and, in relation to the removal or retention and use of an organ after the examination, that they have no actual knowledge that the adult was unwilling for the activity in question to be carried out.

73. Subsections (7) and (8) provide that authorisation can be withdrawn by the nominated person or person with parental rights and responsibilities in writing in the presence of two

witnesses. In the case of a nominee withdrawing their authorisation in writing, neither of the witnesses to that writing can be another nominee.

Section 28 – Authorisation of post-mortem examination etc as respects child under 12 years of age

74. Section 28 relates to a child who dies under 12 years of age. Subsection (1) enables a person who had parental rights and responsibilities in relation to such a child immediately before the child's death to authorise a post-mortem on the child after the child's death. Such a person can also authorise the removal and retention of organs for the purposes of section 23(2)(a) (audit, education, training or research).

75. Subsection (2) provides that where such authorisation is given by a person with parental rights and responsibilities in relation to the child, that authorisation must be in writing, signed and witnessed by 2 witnesses. Authorisation may be subsequently withdrawn in writing, signed and witnessed by one witness.

Section 29 – Nomination of person under section 25(1) or 27(1): additional provisions

76. Subsection (1) sets out the additional formalities relating to the appointment of a nominee by an adult under section 25(1) (authorisation of post-mortem examination etc, by adult's nominee) child or by a child 12 years of age or over under section 27(1) (authorisation of post-mortem examination etc as respects child 2 years of age or over by nominee). Such nominations must be both made and withdrawn by the adult or child in writing signed by the adult or child in the presence of one witness. A witness cannot be another nominee.

77. Subsection (2) provides that a person nominated by an adult under section 25(1) or by a child 12 years of age or over in terms of section 27(1) cannot act under the nomination if the purported nominee is not an adult. A person nominated under those sections is entitled to renounce the nomination.

78. Subsection (3) provides that where more than one person is so nominated, authorisation can be given by any one of the nominees or by all of the nominees acting together.

Section 30 – Post-mortem examination and removal and retention of organs: further requirements

79. Subsection (1) provides that a person cannot carry out a post-mortem examination nor can they remove, retain or use any organs for any of the purposes specified in section 23(2)(a) (audit, education, training or research) unless they have satisfied themselves that it has been duly authorised in accordance with the relevant sections and, as regards the carrying out of the examination the consent of the fiscal has been given where required.

80. Subsection (3) provides that the person intending to carry out the post-mortem examination or any other activity referred to in subsection (1) is entitled to be satisfied that the relevant authorisation is in place in certain specified circumstances. The authorisation forms which will be prescribed by regulations under section 47 will be adapted to make sure they reflect each of the requirements which are set out in this subsection in relation to written authorisations.

81. Paragraph (a) applies to both written and verbal authorisations under Part 2 of the Bill. Paragraphs (b), (d), (e), (f) and (g) all relate to written authorisations under various provisions in Part 2. These paragraphs reflect the fact that the person proposing to carry out the activity will need to know when it is acceptable for them to proceed, in the light of the fact that, under section 32, an offence will be committed if the activity is not authorised by the relevant provision in Part 2.

82. Paragraph (c) relates to verbal authorisation by an adult under section 24(1). In such cases, there requires to be what the person proposing to carry out the activity considers to be an appropriate record of the authorisation by the adult. The person is also entitled to be satisfied that the removal is authorised in accordance with section 24(1) if the verbal authorisation bears from the record to be as respects the deceased adult, to authorise the activity (and to authorise the purpose in certain cases) and to have been expressed verbally in the presence of two adult witnesses. Again, this provision reflects the fact that the person proposing to carry out the activity will need to know when it is safe for them to proceed, in light of the offence provisions. What is or is not an appropriate record of the verbal authorisation is a matter to be determined by the person proposing to carry out the activity. "Appropriate record" is not defined for the purposes of this provision, to avoid being too prescriptive and thereby allow for advancing technology over time in relation to recording devices.

Section 31 – Organ or tissue sample removed before day on which section 22 comes into force

83. Section 31 provides that an organ or tissue sample removed from the body of a deceased person during an examination carried out prior to the authorisation requirements of section 22 coming into force and held immediately before that day for any purpose set out in section 19(a) to (d) can continue to be retained for any or all of those purposes. The examination in question must, however, have had the characteristics of a post-mortem examination under the Bill.

Section 32 – Offences: post-mortem examinations

84. Subsection (1) provides that a person commits an offence if that person carries out a post-mortem examination which has not been authorised, or removes or retains an organ at post-mortem examination without that removal or retention having been authorised in accordance with sections 24, 25, 26, 27, or as the case may be 28. It is a defence under subsection (2) that the person reasonably believed these activities to have been duly authorised.

85. Subsection (3) provides that a person guilty of an offence under subsection (1) will be liable on summary conviction to imprisonment for a term not exceeding 12 months, to a fine not exceeding level 5 on the standard scale or both. On conviction on indictment, that person will be liable to imprisonment for a term not exceeding 3 years to a fine not exceeding level 5 on the standard scale or both.

PART 3: TISSUE SAMPLE OR ORGANS NO LONGER REQUIRED FOR PROCURATOR FISCAL PURPOSES

Section 33 – Tissue sample becoming part of medical records of deceased person

86. Section 33 provides, in relation to examinations carried out for the purposes of the functions or under the authority of the procurator fiscal after the new legislation comes into force, that tissue sample retained from such an examination will become part of the medical record of the deceased

person once the manager of the relevant establishment (see section 36) receives written notice from the fiscal that the sample is no longer required for the purposes of the functions of the fiscal.

Section 34 – Use of tissue sample which has become part of deceased’s medical records

87. Section 34 provides that where, as a result of receipt of notice under section 33, a tissue sample has become part of the deceased’s medical records, it can be used for purposes of diagnosis and audit without authorisation, and for purposes of education, training or research with appropriate authorisation under Part 3.

Section 35 – Use of organ no longer required for procurator fiscal purposes

88. Section 35 provides, in relation to examinations carried out for the purposes of the functions or under the authority of the procurator fiscal after the new legislation comes into force, that an organ removed from the body during such an examination can be retained and used for education, training and research, once the manager of the relevant establishment receives notice from the fiscal that the organ is no longer required for the purposes of the functions of the fiscal, if the subsequent use of the organ for such purposes is authorised in the appropriate manner under Part 3, and if the use is research the research is in addition approved by such person (or persons) or group (or groups) of persons as the Scottish Ministers may specify by order under the section. The intention is that the order will specify a Research Ethics Committee.

Section 36 – Notice under section 33(2) or 35(2)(a): further provisions

89. Section 36 sets out the formalities associated with the notification which the fiscal is to send indicating that tissue samples or organs are no longer required for the purposes of the functions of the fiscal. Subsection (1) provides for the ways in which notification may be sent and subsections (2) and (3) provide a definition of the manager of an establishment for the purposes of section 33(2) or 35(2)(a).

Section 37 – Authorisation of use etc after examination: adult

90. Section 37(1) provides that an adult may authorise the use of tissue sample, or the retention and use of an organ, which is removed from the adult’s body after the adult’s death when that sample or organ is no longer required for the purposes of the functions of the fiscal. The requirement of authorisation applies to use for the purposes of education, training or research (sections 34(b) and 35(2)(b)). Subsection (2) provides that such authorisation must be in writing and signed by the adult and may be withdrawn in writing signed by the adult.

Section 38 – Authorisation of use etc after examination: adult’s nearest relative

91. Section 38(1) provides that where no authorisation by the adult of any of the matters referred to in section 37(1) (use of tissue sample or retention and use of an organ which is no longer required for the purposes of the fiscal) is in force immediately before the adult’s death, the nearest relative of the deceased adult may authorise one or more of those matters. Authorisation is needed where the use relates to the purposes of education, training or research (sections 34(b)).

92. Subsections (2) and (3) provide that such authorisation by the nearest relative must be in writing, signed by the nearest relative and may be withdrawn in writing, signed by the nearest

relative and witnessed by one witness. Subsection (2) also provides that, in providing authorisation, the nearest relative must state that they have no actual knowledge that the adult was unwilling for the matter in question to be authorised for the purpose in question.

Section 39 – Authorisation of use etc after examination: child 12 years of age or over

93. Section 39(1) provides that a child who is 12 years of age or over may authorise the use of tissue sample, or the retention and use of an organ, which is removed from the child's body after the child's death when that sample or organ is no longer required for the purposes of the functions of the fiscal. Authorisation is needed where the use relates to the purposes of education, training or research (sections 34(b)). Subsection (2) provides that such authorisation by the child must be in writing, signed by the child and witnessed by 2 witnesses and may be withdrawn in writing signed by the child.

Section 40 – Authorisation of use etc after examination: person with parental rights and responsibilities for child 12 years of age or over

94. Section 40(1) provides that if there in force immediately before the death of a child who died 12 years of age or over no authorisation by the child of any of the matters referred to in section 39(1) (use of tissue sample or retention and use of an organ which is no longer required for the purposes of the fiscal) a person who immediately before the child's death had parental rights and responsibilities in relation to the child may authorise one or more of those matters. Authorisation is needed where the use relates to the purposes of education, training or research (sections 34(b)).

95. Subsections (2) and (3) provide that such authorisation by the person with parental rights and responsibilities in relation to the child must be in writing, signed by that person and witnessed by 2 witnesses and may be withdrawn in writing by the person who gave authorisation and witnessed by 2 witnesses. Subsection (2) also provides that, in providing authorisation, the person with parental rights and responsibilities must state that they have no actual knowledge that the child was unwilling for the matter in question to be authorised for the purpose in question.

Section 41 – Authorisation of use etc after examination: person with parental rights and responsibilities for child under 12 years of age

96. Section 41(1) provides that where a child dies under 12 years of age, authorisation of one or more of the matters referred to in section 39(1) (use of tissue sample or retention and use of an organ which is no longer required for the purposes of the fiscal) can be given by a person who immediately before the death of the child had parental rights and responsibilities in relation to the child. Authorisation is needed where the use relates to the purposes of education, training or research (sections 34(b) and 35(2)(b)). Subsection (2) provides that authorisation by the person with parental rights and responsibilities must be in writing, signed by that person and witnessed by 2 witnesses and may be withdrawn in writing, signed by the person who gave authorisation and witnessed by one witness.

Section 42 – Use of tissue sample removed before day on which section 33 comes into force

97. Section 42 deals with tissue samples removed from the body of a deceased person as a result of an examination carried out for the purposes of the functions or under the authority of the fiscal before the new legislation comes into force and held immediately before that day for use for any of

the purposes set out in section 34(b) (education, training or research) (whether or not held then also for the purposes of the functions of the fiscal). It provides that such a sample can be retained and used for any of those purposes after the new legislation comes into force without authorisation. Its use for purposes of education, training or research does not preclude its continued use for the purposes of the functions of the fiscal.

Section 43 – Use of organ removed before day on which section 35 comes into force

98. Section 43 deals with organs removed from the body of a deceased person as a result of an examination carried out for the purposes of the functions or under the authority of the fiscal before the new legislation comes into force and held immediately before that day for use for the purposes of existing approved research (whether or not held then also for the purposes of the functions of the fiscal).

99. Subsection (1) provides that such an organ can be retained and used without authorisation for the purposes of the existing approved research or for the purposes of education, training or new approved research after the new legislation comes into force. Its use for purposes of education, training or research does not preclude its continued use for the purposes of the functions of the fiscal. Subsection (2) provides that “existing approved research” means research approved before the new legislation (section 35) comes into force by such person (or persons) or group (or groups) of persons as the Scottish Ministers may specify by order. “New approved research” means research approved after the new legislation (section 35) comes into force by such person (or persons) or group (or groups) of persons as the Scottish Ministers may specify by order. The intention is that the order will specify that such research is to be approved by a Research Ethics Committee.

PART 4: PARTS 1 TO 3: SUPPLEMENTARY PROVISION

Section 44 – Conditions attached to authorisation

100. Section 44(1) provides that conditions can be attached to the following authorisations under Parts 2 and 3: authorisation by a nominee of an adult under section 25(1) or the nominee of a child who died 12 years of age or over under section 27(1); an authorisation by the nearest relative of an adult under section 25(2) or 38(1); an authorisation under section 27(2) or 40(1) by a person who immediately before the death of a child who died 12 years of age or over had parental rights and responsibilities in relation to that child; an authorisation under section 28(1) or 41(1) by a person who immediately before the death of a child under 12 years of age had parental rights and responsibilities in relation to that child.

101. In addition, subsection (1) provides that conditions can be attached to the following authorisations under Part 1: an authorisation by the nearest relative of an adult under section 7(1); an authorisation under section 10(1) by a person who immediately before the death of a child who died 12 years of age or over had parental rights and responsibilities in relation to that child; an authorisation under section 11(1) by a person who immediately before the death of a child under 12 years of age had parental rights and responsibilities in relation to that child. The provision is drafted so that conditions cannot be attached when the purpose is transplantation.

102. Subsection (2) requires that where conditions are attached by virtue of subsection (1), the matter authorised must be carried out in accordance with those conditions, in so far as it is

reasonably practicable to do so. The standard authorisation form for hospital post-mortem examinations allows for the making of such conditions.

Section 45 – Nearest relative

103. Section 45 sets out the arrangements for determining the person's nearest relative, who should be approached for authorisation where appropriate. The hierarchy is very similar to that included in recent mental health legislation (Mental Health (Care and Treatment)(Scotland) Act 2003). Subsection (1) provides who may be the nearest relative of a deceased adult for the purpose of sections 7 (Part 1) and 25 (Part 2). Subsection (2) provides that, in relation to authorisation by the deceased relative of a deceased adult under section 38 (Part 3) in the context of tissue samples or organs no longer required for the purposes of the fiscal, there is an addition to the hierarchy of someone who had a longstanding professional relationship with the adult. Subsection (3) provides that the relationships listed in the different paragraphs of subsection (1) rank in the order of those paragraphs. Subsection (4) sets out the arrangements for determining how authorisation may be given where more than one person falls within a paragraph in subsection (1). Subsection (5) sets out the circumstances in which a person's relationship with the deceased adult is to be left out of account.

Section 46 – Witnesses: additional provisions

104. Section 46 provides for additional requirements which must be satisfied in relation to witnessing, including requirements that a witness must be an adult, that where 2 witnesses are required they must be present at the same time, and certification that a child 12 years of age or over giving authorisation or appointing a nominee understands the effect of the authorisation and is not acting under undue influence. A similar certification is required where an adult appoints a nominee by virtue of section 25(1).

Section 47 – Power to prescribe forms and descriptions of persons who may act as a witness

105. Section 47 gives the Scottish Ministers power to prescribe by regulations the forms of authorisations by nominees or nearest relatives, and the type of people who can act as witnesses in certain cases.

PART 5: AMENDMENT OF THE ANATOMY ACT 1984

Section 48 – Amendment of the Anatomy Act 1984

106. Section 48 of the Bill amends the Anatomy Act 1984 (c.14) ("the 1984 Act") to change the provisions which govern the use of whole cadavers and body parts for the purpose of anatomical examination in Scotland, in line with similar changes being made in England, Wales and Northern Ireland and with other legislative changes which have taken place since 1984; in particular, changes made by the Human Tissue Act 2004. It also introduces new provisions which, for example, provide a right of appeal for any refusal of a licence by Scottish Ministers for premises to be used for the teaching of anatomy or individuals to become teachers of anatomy and take on new powers to govern the public exhibition of anatomical specimens.

107. Subsection (2) amends section 1 (definitions and scope) of the 1984 Act. Subsection (a) amends the definition of anatomical examination by substituting a new section 1(1) of the 1984 Act.

The new section 1(1) provides that an anatomical examination means macroscopic examination of a body for the purposes of teaching, studying or training in or researching into, the gross structure of the human body or surgical and clinical procedures that involve dissection, removal of body parts and the practice of reconstruction including using artificial body parts. The definition includes examination of a body part for those purposes where it is separated from a body in the course of an anatomical examination into that body. Subsection (b) amends section 1(4) of the 1984 Act so as to exclude examinations instructed by the procurator fiscal or post mortem examinations (as defined by section 19 of the Bill) from the scope of the 1984 Act. Subsection (c) amends section 1(5) of the 1984 Act so as to provide that if part of a body is authorised to be removed from the body of a deceased adult for the purposes of transplantation, research, education, training or audit under various provisions of Part 1 of the Bill, the Bill, rather than the 1984 Act, will apply to the removal and use of the part even if the transplantation, research, education, training or audit consists of or involves anatomical examination.

108. Subsection (3) amends section 2 (control of examination and possession of anatomical examinations) of the 1984 Act. Sub-paragraph (i) of paragraphs (a) and (b) amend subsections (1) and (2) of the section 2 of the 1984 Act to include within their scope new sections 4A of the 1984 Act regarding authorisation of use of a body imported into Scotland for anatomical examination and new section 4B of the 1984 Act regarding additional provision on lawful examinations under sections 4 or 4A. The effect is that sections 2(1) and (2) now provide that no person shall carry out an anatomical examination or have an anatomical specimen in his possession unless it is lawful by virtue of sections 4 to 4B. Sub-paragraph (ii) of paragraph (a) amends section 2(1)(d) of the 1984 Act so as to provide that no person shall carry out an anatomical examination of an imported body unless the death has been registered or recorded (or the equivalent) under the law applicable in the country or the territory in which the person died. Sub-paragraph (ii) of paragraph (b) amends section 2(2)(c) so as to provide that no person shall possess an anatomical specimen of an imported body unless a certificate or other document having equivalent effect has been issued under the law applicable in the country or territory in which the person died. Sub-paragraphs (3)(a)(ii) and (3)(b)(ii) and (3)(c) also repeal references to the provisions of the Births and Deaths Registration Act 1953 (which do not apply to Scotland) in section 2 of the 1984 Act.

109. Subsection (4) amends section 3(3)(b) of the 1984 Act so as to remove the wording in that provision that permits a person to be authorised to carry out an anatomical examination if he carries out the examination in the course of teaching or studying, or researching into morphology. The effect of section 3(3)(b) will therefore be that a person will only be authorised to carry out an anatomical examination under that subsection if at the time of the examination he is either licensed to carry it out under section 3(2)(a) of the 1984 Act or he has permission to carry it out from a person who is so licensed.

110. Subsection (5) amends section 4 of the 1984 Act (lawful examinations). Paragraph (a) provides that only a person who is 12 years of age or over may make a request that his body be used after his death for anatomical examination. Paragraph (b) inserts new subsections 4(1A-1D) of the 1984 Act to make it a requirement that such a request must be made in writing, signed by the person making the request and witnessed by an adult. Alternatively, in relation to such requests by persons who are blind or unable to write, the request may be signed on behalf of that person by another adult. Again, the request must be witnessed by an adult. In the latter case, new section 4(1B) provides that such a request must contain a statement signed by both the signatory and the witness that the person who is blind or unable to write expressed his intention to make the request and requested the signatory to sign on his behalf. New section 4(1D) provides that nothing in 4(1A)(b)

prevents a person who is blind from signing a request under subsection (1) in accordance with paragraph (a) of subsection (1A).

111. Paragraphs (c), (e) and (g) repeal section 4(3), (7), (8), (10), (11) of the 1984 Act, which are related to the circumstances under which a person in possession of a body could authorise it to be used for anatomical examination and the statutory period at the end of which authority under section 4 of the 1984 Act expired. Paragraph (d) repeals the words “this subsection applies only to Scotland” in section 4(6) of the 1984 Act, which requires the consent of the procurator fiscal to be obtained in certain circumstances before authority to use a body for anatomical examination may be given or acted upon. This is consequential upon an amendment made in the Human Tissue Act 2004 which extends the application of section 4(6) in Scotland (by virtue of section 59(5)(c) of the 2004 Act. As the 2004 Act repeals the provisions of the 1984 Act as they relate to England & Wales, and the present Bill will amend the provisions of the 1984 Act as they relate to Scotland, there is no need for section 4(6) to provide that that subsection applies only to Scotland. Paragraph (f) will insert a new subsection 4(9A) of the 1984 Act to provide that subsection 4(9) of that Act (allowing authority to be given in the case of a body lying in a hospital, nursing home, other institution or accommodation provided by a care home service by a person designated by the person having the control and management of the institution) does not apply to the use of an imported body for anatomical examination.

112. Subsection (6) inserts new provisions 4A and 4B into the 1984 Act to govern the lawful use of imported bodies. New section 4A allows a person who is lawfully in possession of an imported body to authorise its use for anatomical examination if it is imported for such use in Scotland, no more than 3 years have elapsed since the date of death and either there has been no previous anatomical examination of the imported body or any such previous examination was only made for the purpose of removal and retention of one or more of the body parts for the purposes of education, training or research. New section 4B makes additional provision in relation to lawful examinations. Subsection (1) of new section 4B provides that no authority may be given in respect of a body under section 4(2) or 4A by a person entrusted with the body for the purpose only of its interment or cremation. Subsections (2), (3) and (4) of new section 4B make additional provision in relation to setting of, and expiry of, the statutory period of 3 years, referred to in new section 4A.

113. Subsection (7) amends section 5(1), (4) and (5) of the 1984 Act (control of possession after examination). Paragraph (a) substitutes a new section 5(1) of the 1984 Act so as to extend the application of that subsection to the authorisation of use of an imported body for anatomical examination under section 4A or situations where a body has been used for anatomical examination outwith Scotland. In addition, it provides that section 5 will apply whether or not the body or part of the body has undergone any process to preserve it. Paragraph (b) extends the scope of section 5(4) of the 1984 Act relating to the circumstances in which section 5(2) of that Act (prohibition of possession of a body or part of the body) does not apply. The effect is that section 5(4) now allows a person to have possession of part of a body whose anatomical examination has been concluded before the expiry of the authority under inserted section 4A of the 1984 Act, as well as before the expiry of authority under section 4(2). In addition, paragraph (b) amends section 5(4) so as to disapply section 5(2) in certain circumstances where a person has possession of part of a body which has been used for anatomical examination outwith Scotland. Paragraph (c) extends the scope of section 5(5) of the 1984 Act so as to provide that a licence may be granted to a person to have possession of parts of bodies in the interests of training, as well as in the interests of education or research.

114. Subsection (8) substitutes a new section 6(3) into the 1984 Act to provide that the authority given under inserted section 4A for use of an imported body for anatomical examination may include authority for possession of parts (or any specified parts) of the body to be held in accordance with the authority after the examination is concluded.

115. Subsection (9) inserts a new section 6A into the 1984 Act. Subsection (1) of new section 6A provides that no person may publicly display an anatomical specimen, a body or part of a body which has either been used for anatomical examination or used outwith Scotland for such an examination, whether or not it has undergone a process to preserve it. Subsection (2) of the new section 6A makes provision as to the circumstances in which section 6A(1) does not apply. Subsection (3) of the new section 6A allows Scottish Ministers to grant a licence to a person to display a body part if they think it desirable to do so in the interests of teaching or studying, or training into, the gross structure of the human body. A person will be authorised to publicly display a body part under section 6A(3), if at the time of the display, he is so licensed. Subsection (4) of the new section 6A provides that a licence-holder under section 6A(3) shall be required to compile and retain such records as may be specified by regulations made by the Scottish Ministers. Subsection (5) of the new section 6A defines the phrase “public display” as including display of a body or part of a body by visual image by means of a electronic communications network but excluding display which enables people to pay their final respects to the deceased or which is incidental to the deceased’s funeral and, in certain circumstances, display at a place of religious worship. Subsection (6) of the new section 6A provides that the power to make regulations under inserted section 6A(4) shall be subject to negative procedure in the Scottish Parliament.

116. Subsection (10) inserts a new subsection (7A) into section 7 of the 1984 Act (licences: general provisions). Paragraph (a) amends section 7(7) so that that subsection is subject to the new inserted section 7(7A). Section 7(7) of the 1984 Act requires revocation of a licence by Scottish Ministers to be accompanied by written notice to the licence holder, specifying the reasons why, and the date on which, the licence is to be revoked (which date must be 28 days from the date of the notice). Inserted section 7(7A) will provide an exception to the application of section 7(7) if Scottish Ministers consider that there would be a risk to public health if the requirements of section 7(7) were to apply. In those circumstances, Scottish Ministers are required to notify the licence holder that the revocation takes effect on the date specified in the notification. The 28 day period of notice is therefore not required in these circumstances.

117. Subsection (11) inserts a new section 7A into the 1984 Act. Subsection (1) of the new section 7A introduces a right of appeal to a sheriff principal against decisions made by Scottish Ministers under various provisions of the amended 1984 Act either to refuse to grant a licence for a particular purpose, to grant a licence subject to conditions or to revoke a licence. Subsections (2) and (3) of the new section 7A will provide that the applicant may appeal on specified grounds to the sheriff principal within 21 days from the date of the decision appealed against. The specified grounds are that the Scottish Ministers in arriving at their decision erred in law, based their decision on an incorrect material fact, acted contrary to natural justice or exercised their discretion in an unreasonable manner. Subsection (4) of the new section 7A specifies the appropriate sheriff principal to which an appeal lies, depending on what type of decision is appealed against. Subsection (5) of new section 7A specifies the disposal powers of the sheriff principal when allowing an appeal under this section. In allowing the appeal, the sheriff principal must set aside the decision and must either substitute his own decision or remit the case to the Scottish Ministers anew.

118. Subsection (12) amends section 8(1) (regulations) of the 1984 Act. Paragraph (a) inserts a reference to the new section 4A (lawful examination: imported bodies) into section 8(1)(a), so that Scottish Ministers may make regulations in relation to bodies the anatomical examination of which is lawful by virtue of either section 4 or 4A, with a view to securing their efficient and orderly examination and the decent disposal of the bodies (or parts of them) after their examination has been concluded. Paragraph (b) substitutes in section 8(1)(b) for the words “lawful by virtue of section 6” the words “authorised under section 5(5)”, so that the scope of regulations that the Scottish Ministers may now make under section 8(1)(b), with a view to securing that they are decently cared for, is narrowed to apply only to body parts which are the subject of a licence under section 5(5). Paragraph (c) expands the regulation making powers of the Scottish Ministers under section 8(1) to reflect the insertion of the new section 6A (control of public display), by inserting a new section 8(1)(c), allowing Scottish Ministers to make regulations in relation to body parts displayed under section 6A(3) with a view to securing that the parts are decently cared for and displayed with appropriate respect.

119. Subsection (13) inserts a new section 8A into the 1984 Act. Subsection (1) of the new section 8A enables Scottish Ministers to prepare a Code of Practice, firstly to give practical guidance to certain persons (those licensed under section 3(2) to carry out anatomical examinations or to have possession of anatomical specimens, those authorised under section 5(5) to have possession of parts of a body, and those authorised under section 6A(3) to publicly display parts of a body) and secondly to lay down standards expected in relation to those specified activities. Subsections (2) to (9) of the new section 8A make further provision in relation to the making of a code of practice. Under subsection (2), a code of practice prepared under (1) may not be given effect unless and until it has been confirmed by order of, and brought into force on a day appointed by order by, the Scottish Ministers; such orders are, under subsection (9), to be made by statutory instrument subject to negative procedure in the Scottish Parliament. Subsection (3) requires the Scottish Ministers to consult such persons as they see fit and to lay a draft of the code before the Scottish Parliament before they confirm it under subsection (2)(a), whilst subsection (4) requires them to thereafter publish a confirmed code of practice in such way as, in their opinion, is likely to bring it to the attention of those interested in it. The Scottish Ministers are also, under subsection (5), required to keep a code of practice confirmed by order under subsection (2)(a) under review and to prepare a revised code of practice where appropriate, with subsection (6) providing that the procedures outlined in subsections (2) to (4) will also apply to such a revised code of practice. Subsection (7) provides that any person licensed or authorised as mentioned in subsection (1)(a) is to have regard to the provisions of a published code of practice in so far as the provisions are applicable to the activity that the person is licensed or authorised to carry out. However, a failure on the part of any such person to comply with any provision of such a code will not of itself render them liable to any proceedings. Subsection (8) enables Scottish Ministers, in carrying out their functions under the 1984 Act with respect to licences, to take into account any relevant observance of, or failure to observe, a code of practice published under subsection (4), so far as dealing with an application for a licence under section 3(2) (to carry out anatomical examinations or to have possession of anatomical specimens), under section 5(5) (to have possession of parts of a body) or under section 6A(3) (to publicly display parts of a body).

120. Subsection (14) removes the reference to her Majesty’s Inspector of Anatomy (to reflect the cessation of that post in England and Wales under the Human Tissue Act 2004) whilst retaining the reference to Her Majesty’s Inspector of Anatomy for Scotland.

121. Subsection (15) amends the powers of HM Inspector of Anatomy for Scotland under section 10 (inspector's powers to inspect records and premises) of the 1984 Act. Paragraph (a) amends section 10(1) to enable an inspector to require the production of, and inspect and take away copies of, any records which a person is required to retain by virtue of the new requirement under section 6A(4) to compile and retain records by holders of a licence granted under section 6A(3) (licence by Scottish Ministers to display part of a body). Paragraph (b) amends subsection (2)(a) of section 10, to extend the powers of an inspector to enter and inspect premises in accordance with that subsection to where he has reasonable cause to believe that an offence under any of the offences listed in section 11(1) has been or is being committed. Paragraph (c) repeals subsection (5) of section 10, which had limited the power to enter premises under subsection (2) to where a licence under section 3(1) is effective in respect of the premises both at the time of the suspected offence and at the time of the entry.

122. Subsection (16) amends section 11 (offences) of the 1984 Act. Paragraph (a) of subsection (16) adds the unlicensed display of a body or part of a body, in contravention of the new section 6A of the 1984 Act, to the list of possible offences under section 11(1) of the 1984 Act. Paragraph (b) adds to the existing listed offences under section 11(5) of the 1984 Act, in relation to record and information keeping, a failure to comply with the new requirement under section 6A(4) to compile and retain records by licence-holders under section 6A(3) (licence by Scottish Ministers to display part of a body). Paragraph (c) amends section 11(9) to add members of bodies corporate to the list of individuals who will be guilty along with the body corporate where the offence was committed with the consent or connivance of or is attributable to any neglect on the part of that person. Paragraph (d) inserts two new subsections (9A) and (9B) into section 11, which will extend to Scottish partnerships and unincorporated associations respectively liability for offences under section 11 or against regulations made under section 8 of the 1984 Act.

123. Subsection (17) inserts a new interpretation section (section 11B) to the 1984 Act to introduce definitions of "adult" and "imported body", terms which are used within the new provisions being inserted into the 1984 Act by virtue of section 48.

PART 6: MISCELLANEOUS

Section 49 – Arrangements by Scottish Ministers for assistance with functions under sections 1, 2, 15(3), 16(2), or 17(3)

124. This section provides that the Scottish Ministers may make arrangements with other UK public authorities to undertake any of their functions under sections 1, 2, 15(3) (except the power to make regulations under that section), 16(2) or 17(3). This would allow the Scottish Ministers to have certain functions carried out by an organisation such as the Human Tissue Authority.

125. Subsection (3) maintains the Scottish Ministers' responsibility for functions carried out under such arrangements.

Section 50 – Power to give effect to Community obligations

126. Section 50 gives the Scottish Ministers power to amend the Bill once it has been enacted by regulations to take account of a Community obligation, such as implementation of the EU Directive on Tissue and Cells. This equates to section 46 of the Human Tissue Act 2004 (c.30).

Section 51 – Bodies Corporate

127. Section 51 includes standard provisions setting out the circumstances in which, where a body corporate or Scottish partnership is charged with an offence under the Act, persons involved with a body corporate or such partnership may also acquire criminal responsibility.

PART 7: GENERAL

Section 52 – Ancillary provisions

128. This section enables the Scottish Ministers to make further provision, by order, which is incidental to or consequent on the Bill and to allow transitional or savings provisions as required in implementing the Bill's provisions.

Section 53 – Regulations or orders

129. Subsection (1) provides that powers to make orders or regulations in the Bill are to be exercisable by statutory instrument. Subsection (2) provides that except where otherwise provided, the statutory instruments containing such orders or regulations shall be subject to negative procedure in the Scottish Parliament. Subsection (3) provides that regulations under section 50 or an order under section 52 which contains provisions which alter the text of an Act are to be the subject of affirmative resolution.

Section 54 – Interpretation

130. This section defines terms used throughout the Bill.

Section 55 – Repeals

131. Section 55 introduces Schedule 1 (which contains consequential repeals).

Section 56 – Short title and commencement

132. This section provides for the short title of the Bill. Further, section 56 allows the Scottish Ministers to bring the provisions of the Bill (except sections 47, 53, 54 and 56) into force by order and to set different dates to commence different provisions. The section provides for sections 47, 53, 54 and 56 to come into force on Royal Assent.

FINANCIAL MEMORANDUM

TRANSPLANTATION AND HOSPITAL POST-MORTEM EXAMINATIONS

Costs on the Scottish Administration

Transplantation

133. National programmes of heart, lung, liver and combined kidney and pancreas transplantation are already funded by the Scottish Executive, at a total cost of some £5m a year. Renal replacement therapy, including renal transplantation, is funded from each Health Board's general allocation. The duties placed on the Scottish Ministers by section 1 are a formalisation of the current arrangements, and the inclusion of those duties in statute will not of itself give rise to any new costs.

134. The Bill provides for the Scottish Ministers to make arrangements with persons to assist in relation to transplantation functions. At present, this function is undertaken for live transplants without charge to Scotland by the Unrelated Live Transplants Regulatory Authority (ULTRA). Under the Human Tissue Act 2004 (c.30) this function will transfer to the Human Tissue Authority. The current number of such transplants in Scotland (around 40 a year, taking account of the anticipated increase in numbers) does not justify the establishment of a separate Scottish body. On grounds of consistency of approach across the UK, the Scottish Ministers wish to use the provision in the Bill to ask the Human Tissue Authority to scrutinise Scottish cases. The Human Tissue Act 2004 (c.30) gives the Human Tissue Authority (HTA) powers to charge for the performance of its functions on behalf of other UK public authorities and the Scottish Executive understands that the HTA will expect to be reimbursed for scrutinising live transplants in Scotland. Until the HTA is fully established it will not be possible to identify what the charges might be. The Department of Health is providing a budget of £2m a year to meet the HTA's overall costs in this and the next 2 financial years. Based on this, it is estimated that a maximum of around £50,000 per year will fall on the Scottish Administration through the charging of fees for scrutinising Scottish cases. As the HTA will be carrying out a wide range of functions which do not apply in Scotland, a contribution considerably less than the standard 10% seems an appropriate estimate.

135. The framework set out in the Bill is expected to lead to an increase in the organ donation rate in Scotland, and therefore in the number of transplant operations performed. As each of the transplant programmes is geared to accommodate variations in the number of procedures undertaken, we would not expect the additional operations to generate additional expenditure. Any increased costs to Boards associated with the maintenance of a larger number of recipients post-transplant would be offset by the fact that kidney transplantation is much more cost-effective than renal dialysis. It is estimated that each kidney transplant saves NHS Scotland around £25,000 a year in hospital haemodialysis costs, and in 2004, 111 kidney transplants were performed in Scotland.

Hospital Post-Mortem Examinations

136. Very few hospital post-mortem examinations are currently being performed. As one of the main effects of the Bill is intended to be a revival of confidence in the process on the part of the public and NHS staff, the expectation is that the number of these examinations will increase. This is not of itself expected to create additional expenditure, since the staff and services are already in

place and would be able to cope with a gradual increase. The increase in the number of examinations will only come about, however, if the standard forms are in place, and staff are properly trained to discuss them with families.

137. The Bill will give the Scottish Ministers the power to prescribe forms for obtaining authorisation. The intention is that the power will be used to bring to an end the use of local forms by introducing across Scotland a standard form for authorising a hospital post-mortem examination. There will be separate forms for adult and paediatric post-mortem examinations, accompanied by 2 standard information leaflets, one giving general information, the other going into greater detail for those who wish it. These arrangements are a response to the importance attached by the family support groups to addressing inconsistencies of approach which they regarded as one of the particularly distressing features of past practice. The new forms have to be sensitive to the amount of information needed in each case, and this highlights the importance of good design, in addition to the thought which has been given to the content of the forms. The cost of producing an initial stock of forms and leaflets would be some £250,000, based on issuing a supply of 100 of each of adult and paediatric forms and of each leaflet to each of the hospitals in Scotland.

138. Training will be required for hospital staff who will have to go through the form with families. No such training programmes exist at present and the Executive will require to work with the agencies responsible for the training of health professionals to develop a suitable programme, drawing wherever possible on training packages being developed in England to ensure consistency of approach. The initial costs involved could be in the region of £100,000 - £150,000, covering the specification for the course and the provision of training materials. Some hospitals may already be providing this service but this additional expenditure will make training materials available to all health professionals in Scotland.

Costs on Local Authorities

139. The transplantation and hospital post-mortem examination provisions of the Bill have no financial implications for local authorities.

Costs on Other Bodies, Individuals and Businesses

140. The provisions of the Bill relating to transplantation will not have any direct financial consequences on Health Boards as they concern the creation of a framework within which people can make decisions about transplantation, rather than being directly related to the provision of services.

141. Health Boards will have to cover the cost of replacing the forms for authorising a hospital post-mortem examination once the initial stocks supplied by the Department are exhausted. However this is unlikely to cost significantly more than the cost of replenishing the existing forms.

142. There may be a need to provide some refresher training for medical staff on generic issues, such as end-of-life matters, including the process of death certification and an awareness of the types of hospital death which have to be reported to the Procurator Fiscal. However such training is already being provided at under- and post-graduate levels and through on-the-job training by the bodies responsible for professional education and training, in particular the medical and nursing schools, the Royal Colleges and NHS Education for Scotland. Such refresher training already

forms part of these bodies remit and therefore the costs of any refresher training is already covered by existing provision. Maximum use will be made of techniques such as web-based training, in order to achieve the best value for money.

AMENDMENT OF THE ANATOMY ACT 1984

Costs on the Scottish Administration

143. At present there is a single individual who acts as HM Inspector of Anatomy for Scotland, England and Wales. His salary, accommodation and administrative assistance are provided by the Department of Health on a UK basis and the costs to the Executive only amount to travel and subsistence for annual visits to Scottish Schools of Anatomy. On average these do not exceed £500 a year. However HM Inspectors duties in England and Wales will now be subsumed into the new Human Tissues Authority. It will be necessary for the Executive to continue to make arrangements for inspection. For example they may enter into a contract with the Human Tissues Authority, or any successor body, or any other qualified body or person, to provide inspection services. This is likely to lead to increased costs, estimated at £20,000 - £25,000. This figure allows for 5 inspection visits a year, the salary cost of the Inspector for his Scottish duties, a contribution towards accommodation, and administrative expenses. It is our best estimate at this stage of the likely cost for the inspection arrangements.

Costs on Local Authorities

144. The amendments to the Anatomy Act 1984 provisions of the Bill have no financial implications for local authorities.

Costs on Other Bodies, Individuals and Businesses

Anatomy Departments

145. There would be no costs for Anatomy Departments. The provisions of the Bill which allow training in surgical techniques to be carried out using donated bodies may produce minor savings, since it may no longer be necessary to purchase models for this purpose, but they cannot be quantified easily.

ANNEX

Summary of additional costs arising from the Bill

Policy Area	Cost on Scottish Administration	Health Boards	Local Authorities	Cost on other Bodies	Paragraph Reference
Transplantation etc.	£50,000 p.a. for HTA charges.	Nil	Nil	Nil	134
	£250,000 for forms and leaflets.	Nil	Nil	Nil	137
		Nil	Nil	£100,000 - £150,000 for developing training	138
Amendments to the Anatomy Act 1984	£20,000 – £25,000 p.a. for inspections by the HMIA.	Nil	Nil	Nil	143

EXECUTIVE STATEMENT ON LEGISLATIVE COMPETENCE

146. On 2 June 2005, the Minister for Health (Mr Andy Kerr MSP) made the following statement:

“In my view, the provisions of the Human Tissue (Scotland) Bill would be within the legislative competence of the Scottish Parliament.”

**PRESIDING OFFICER’S STATEMENT ON LEGISLATIVE
COMPETENCE**

147. On 2 June 2005, the Presiding Officer (Rt Hon George Reid MSP) made the following statement:

“In my view, the provisions of the Human Tissue (Scotland) Bill would be within the legislative competence of the Scottish Parliament.”

These documents relate to the Human Tissue (Scotland) Bill (SP Bill 42) as introduced in the Scottish Parliament on 3 June 2005

HUMAN TISSUE (SCOTLAND) BILL

EXPLANATORY NOTES

(AND OTHER ACCOMPANYING DOCUMENTS)

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