

HUMAN TISSUE (SCOTLAND) ACT 2006

REVISED EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes have been prepared by the Scottish Executive in order to assist the reader of the Human Tissue (Scotland) Act 2006 (“the Act”). They do not form part of the Act and have not been endorsed by the Parliament.
2. The Notes should be read in conjunction with the Act. They are not, and are not meant to be, a comprehensive description of the Act. 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 ACT – AN OVERVIEW

3. The main provisions of the Act 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 Act, 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.

4. 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

5. 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

6. 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 or 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 is authorised to do so in accordance with regulations made by the Scottish Ministers (section 12(1)). 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

7. Section 4 makes clear that none of the relevant provisions of Part 1 of the Act apply in certain circumstances. They do not affect 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. They do not 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. Nor do they apply to the removal, retention or use of part of a deceased person's body if the person died at least 100 years before section 3 comes into force.

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

8. Subsection (1) 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 is or 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), except with the consent of the procurator fiscal. Subsection (2) provides that for the purposes of subsection (1), the fiscal's consent can be given verbally, provided it is confirmed in writing as soon as reasonably practicable.

Section 6 – Authorisation: adult

9. 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 one or more of the purposes specified in section 3(1) (transplantation, research, education or training or audit). Subsection (2) provides that such authorisation may be in writing or can be given verbally, thus ensuring that an adult can express authorisation for transplantation over the telephone. Authorisation can be withdrawn, but the withdrawal must be in writing. Subsection (3) provides that if the adult is blind or unable to write, such written withdrawal may be signed by another adult on behalf of the adult who is unable to write. If it is so signed, it must be witnessed by one witness. Subsection (4) provides that withdrawal of authorisation by virtue of subsection (3) must contain a statement signed by both the signatory and the witness that the person who is blind or unable to write expressed his or her intention to withdraw the authorisation and requested the signatory to sign the withdrawal on his or her behalf. Subsection (5) provides that nothing in subsection (3) prevents an adult who is blind from withdrawing authorisation in accordance with paragraph (b) of subsection (2). Subsection (6) provides that for authorisation in writing under section 6(2)(a)(i), "writing" includes representation of a character in visible form. The effect of this provision is that authorisation provided via the NHS Organ Donor Register, Organ Donor cards or any other method of tick box authorisation will come within the scope of authorisation by the adult "in writing" for the purposes of section 6(2)(a)(i).

Section 7 – Authorisation by adult’s nearest relative

10. 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), subject to the terms of section 7(4).

11. Section 7(2) provides that if there is in force immediately before an adult’s death authorisation by the adult 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, subject to the terms of section 7(4).

12. 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 or audit, subject to the terms of section 7(4).

13. 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.

14. 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.

15. Section 7(6)(a) provides that authorisation by virtue of subsections (1), (2) and (3) must be in writing and signed, or may be expressed verbally by the nearest relative. Paragraph (b) of subsection (6) provides that such authorisation for the purposes of research, education, training or audit may be withdrawn in writing and signed by the nearest relative.

16. Section 7(7) prevents the withdrawal of authorisation given by an adult’s nearest relative under section 7(1) for the purposes of transplantation.

Section 8 – Authorisation: child 12 years of age or over

17. 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. Subsection (3) provides that if the child is blind or unable to write, such authorisation and the withdrawal of such authorisation may be signed by an adult on the child’s behalf and witnessed by one witness. Subsection (4) provides that such authorisation or withdrawal of authorisation

must contain a statement signed by both the adult and the witness that the child expressed the intention to either give or withdraw the authorisation and requested the adult to sign on his or her behalf. Subsection (5) provides that any such authorisation on behalf of a child 12 years of age or over who is blind or unable to write must contain or be accompanied by certification from both the adult and the witness that in their opinion the child understands the effect of the authorisation and is not acting under undue influence in giving it. Subsection (6) provides that nothing in subsection (3) prevents a child who is blind from giving or withdrawing authorisation in accordance with paragraph (a) or (b) of subsection (2). In the situation whereby authorisation is giving in writing by the child himself or herself under section 9(2)(a), rather than by a signatory on the child's behalf, subsection 9(7) provides that "writing" includes representation of a character in visible form. The effect of this provision is that such authorisation provided via the NHS Organ Donor Register, Organ Donor cards or any other method of tick box authorisation will come within the scope of authorisation by the child "in writing" for the purposes of section 9(2)(a).

Section 9 – Authorisation as respects child who dies 12 years of age or over by person with parental rights and responsibilities

18. Section 9 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 (but who is not a local authority) may authorise the removal and use of any part for one or more of the purposes of transplantation, education or training, research or audit.

19. Subsections (2) to (5) repeat, in the context of those who had parental rights and responsibilities in relation to a child who died 12 years or older immediately before the child's death, the provisions relating to authorisation by an adult's nearest relative, as described in paragraphs 12 to 15 above.

20. Subsection (6)(a) provides that authorisation by virtue of subsections (1), (2) or (3) of section 9 must be in writing and signed, or expressed verbally, by the person giving the authorisation Paragraph (b) of subsection (6) provides that such authorisation given for the purposes of research, education, training or audit may be withdrawn in writing and signed by the same person who gave the authorisation.

21. Subsection (7) provides that authorisation given by a person by virtue of section 9(1), for the purposes of transplantation, cannot be withdrawn.

Section 10 – Authorisation as respects a child who dies under 12 years of age

22. Section 10(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 but who is not a local authority. Section 10(2)(a) provides that such authorisation must be in writing and signed, or expressed verbally, by the person who provides the authorisation. Paragraph (b) of subsection (2) provides that such authorisation given for the purposes of research, education, training or audit may be withdrawn in writing and signed by the same person who gave the authorisation.

Section 10(3) provides that authorisation given by a person by virtue of section 10(1) for the purposes of transplantation cannot be withdrawn.

Section 11 – Removal of part of body of deceased person: further requirements

23. Section 11(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 11(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 11(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. 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. Section 11(5)(g) will apply only where the authorisation has been signed by the child under section 9(1) and not where it has been signed by an adult on their behalf.

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 Act. Paragraph (k) relates to written authorisation which has been signed by an adult under section 9(1) on behalf of a child who is 12 years of age or over and who is blind or unable to write. 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 16, 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

by the adult. Similarly, paragraphs (e), (g) and (i) relate to verbal authorisation by an adult's nearest relative under section 7(1), (2) and (3) respectively. Paragraphs (m), (o) and (q) relate to verbal authorisation under section 9(1), (2) or (3) respectively by a person who, immediately before the death of a child who died 12 years of age over, had parental rights and responsibilities in relation to that child. Paragraph (l) relates to verbal authorisation under section 10(1) by a person who, immediately before the death of a child who died under 12 years of age, had parental rights and responsibilities in relation to that child. In such cases, there requires to be what the person undertaking the removal (or the practitioner as the case may be) considers to be an appropriate record of the verbal authorisation. In each of these cases, the person or practitioner is entitled to be satisfied that the removal is authorised in accordance with the relevant authorisation provision if the authorisation bears from that record to demonstrate the matters listed in the relevant paragraph. Again, these provisions reflect 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 12 – Removal of tissue sample to determine viability of transplantation

29. Section 12A permits a person removing a part of the body of a deceased person in accordance with an authorisation under Part 1 of the Act for transplantation, to remove and secure the examination of such tissue sample from the body that the person considers necessary or expedient to determine the viability of the transplantation.

Section 13 – Preservation for transplantation

30. Section 13 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. Subsection (1) provides that where part of a deceased person's body may be suitable for transplantation, the managers of the premises may take steps to preserve the part for use for transplantation and may retain the body for that purpose. However, they may not move the part or body to other premises. Subsection (2) provides that the minimum steps necessary should be taken to preserve the body, and the least invasive procedure used. Subsection (3) provides that authority under subsection (1) extends to any person authorised to act under the authority by the managers of the premises in question and makes clear that preservation must be stopped as soon as it becomes clear that no authorisation will be given for transplantation.

31. Subsections (4) and (5) define the premises where such procedures may be carried out. These premises are a health service hospital and premises in which a registered independent health care service is provided.

Section 14 – Part of body removed before day on which section 3 comes into force

32. Section 14 provides that part of a deceased person's body which is removed for the purposes of transplantation, research, education, training or audit before section 3 comes into

force, other than during a post mortem or anatomical examination, and which is held immediately before that day for any of those purposes may be retained and continue to be used for any such purpose.

Section 15 – Existing request by adult not acted on before commencement of sections 3 and 6.

33. Section 15 extends only to requests that have been made by an adult that part of their body be used after their death for transplantation but which have not yet been acted upon at the time sections 3 and 6 come into force. Subsection (1) provides that where such a request is in force, either in writing or expressed verbally by the adult, the request is to be treated for the purposes of Part 1 as if it were authorisation by the adult in accordance with section 6(1), either in writing or, as the case may be, expressed verbally. Subsection (2) provides that a request “in writing” for the purposes of subsection (1) includes representation of a character in visible form. The effect of this provision is that existing on-line registration by an adult on the NHS Organ Donor Register, whether given verbally (over the telephone) or in writing, can be treated as if it were authorisation in accordance with section 6. Existing requests made via Organ Donor cards or other methods of tick box requests will also come within the scope of existing requests by an adult “in writing” for the purposes of this section.

Section 16 – Offences: removal or use of part of body of deceased person for transplantation, research, etc

34. Section 16(1)(a) provides that it is an offence to remove a part of the body of a deceased person for the purposes of transplantation, research, education, training or audit after the day on which section 3 comes into force, or to use after that day any part so removed for any such purpose, without having the necessary authorisation in accordance with section 6, 7, 8, 9 or 10.

35. Paragraph (b) of subsection (1) provides that it is an offence if such removal or use is undertaken by someone who is not either a registered medical practitioner, or a person authorised to undertake such a removal in terms of regulations under section 11(1), or if the person undertaking the removal has not satisfied himself that life is extinct in terms of section 11(4)(a).

36. 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 the removal and use had been authorised in accordance with the relevant section of the Act or that the requirements of section 11(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).

37. Subsection (3) sets out the penalties attaching to an offence under section 16(1). It 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 the statutory maximum, or both. On conviction on indictment, that person will be liable to imprisonment for a term not exceeding 3 years, to a fine, or both.

Section 17 – Restrictions on transplants involving live donor

38. 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. A child, or an adult with incapacity cannot be a living donor of an organ or part of an organ except in the context of a domino transplant operation and cannot be a living donor of any tissue other than regenerative tissue.

39. Section 17(1)(a) makes it an offence, subject to subsections (3), (4), (5) and (8) to remove an organ, part of an organ or tissue from a living child with the intention that it be used for transplantation. (“Adult” means a person 16 years of age or over and “child” means a person under the age of 16 – section 60(1).) Section 17(1)(b) makes it an offence, subject to subsections (3), (4), (5) and (8) to remove an organ or part of an organ from a living adult with the intention that it be used for transplantation. Section 17(1)(c) makes it an offence, subject to subsections (3), (4), (5) and (8) to remove any tissue from a living adult with incapacity with the intention that it be used for transplantation. In each case, 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 child, a living adult or, as the case may be, a living adult with incapacity.

40. Section 17(2)(a) makes it an offence, subject to the provisions of subsections (3), (4), (5) and (8), to use for transplantation, an organ or part of an organ or any tissue which has come from the body of a living child. Section 17(2)(b) makes it an offence, subject to subsections (3), (4), (5) and (8) to use for transplantation an organ or part of an organ from a living adult. Section 15(2)(c) makes it an offence, subject to subsections (3), (4), (5) and (8) to use for transplantation any tissue from a living adult with incapacity. 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 of the organ or tissue has come from a living child, a living adult or, as the case may be, a living adult with incapacity.

41. 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 20 (prohibition of commercial dealings in parts of a human body for transplantation) and that such other conditions or 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 (8)).

42. Subsection (4) gives the Scottish Ministers power by regulations to provide that no offence is committed under subsection (1)(a) or (c) (in relation to removal of an organ, part of an organ or tissue from the body of a living child or the removal of any tissue from the body of a

living adult with incapacity intending that it be used for transplantation) or that no offence is committed under subsection (2)(a) or (c) (in relation to using for transplantation an organ or part of an organ which has come from the body of a living adult or using for transplantation any tissue which has come from the body of a living adult with incapacity) where the requirements mentioned in subsection (4) are met. The requirements are that a person removes or uses regenerative tissue and that Scottish Ministers are satisfied that no reward has been or will be given in contravention of the provisions of section 20 and that such other conditions or requirements as may be specified in the regulations are complied with. Again, where regulations provide for such an exception from the offence provisions in subsections (1)(a) or (c) or (2)(a) or (c), it is sufficient if the person reasonably believes that the exception applies (subsection (8)).

43. Subsection (5) gives the Scottish Ministers power by regulations to provide that no offence is committed under subsection (1)(a) or (b) (in relation to removal of an organ, part of an organ or tissue from the body of a living child or the removal of an organ or part of an organ from the body of a living adult intending that it be used for transplantation) or that no offence is committed under subsection (2)(a) or (b) (in relation to using for transplantation an organ, part of an organ or any tissue which has come from the body of a living child or using for transplantation an organ or part of an organ which has come from the body of a living adult with incapacity) where the requirements mentioned in subsection (5) are met. The requirements are that a person removes from a child or an adult with incapacity an organ or part of an organ during a domino organ transplant operation which is in turn intended to be used for transplantation in respect of another living person, or uses an organ or part of an organ so removed, that Scottish Ministers are satisfied that no reward has been or will be given in contravention of the provisions of section 20 and that such other conditions or requirements as may be specified in the regulations are complied with. Again, where regulations provide for such an exception from the offence provisions in subsection (1)(a) or (b) or (2)(a) or (b), it is sufficient if the person reasonably believes that the exception applies (subsection (8)).

44. Subsection (4) provides that in making regulations under subsection (3), (4) and (5) the Scottish Ministers must include a provision allowing for appeals against decisions relating to matters dealt with by the regulations.

45. “Adult with incapacity” for the purposes of subsections (1)(c) and (2)(c), is defined in subsection (7) as an adult to whom section 17 applies and, for the purposes of the provisions dealing with domino organ transplant operations, an adult who has been assessed as incapable under section 47 of the Adults with Incapacity (Scotland) Act 2000. “Domino organ transplant operation” is defined to ensure that the transplant operation must firstly be for the benefit of the child or adult with incapacity as the primary focus.

46. “Regenerative tissue” is defined in subsection (10) as tissue which, after injury or removal, is replaced by the body of the living person by natural processes. “Reward” is defined in subsection (10) 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.

47. Subsection (9) sets out the penalties attaching to an offence under section 15. It provides that a person guilty of an offence under this section 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.

Section 18 – Meaning of adult with incapacity for purposes of section 17(1)(c) and (2)(c)

48. Subsection (1) provides that for the purposes of section 17(1)(c) and (2)(c), an adult with incapacity is an adult who is incapable in relation to a decision about the removal from the adult of regenerative tissue for the purposes of transplantation. In addition, Scottish Ministers must have issued a certificate in accordance with subsection (2) that they are of this opinion. Subsection (2) provides that such a certificate must specify the period during which it is in force, which can be a period of up to one year from the date of the certificate. Subsection (3) provides that “incapable” in this section has the same meaning as it has in section 1(6) of the Adults With Incapacity (Scotland) Act 2000.

Section 19 – Records, information etc.: removal and use of parts of human bodies for transplantation etc.

49. 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).

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

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

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

53. 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.

54. Subsection (5) sets out the penalties attaching to an offence under subsections 16(4)(a) or (b). It provides that a person guilty of an offence under subsection (4)(a) will be liable on summary conviction to a fine not exceeding level 3 on the standard scale, and that a person guilty of an offence under subsection (4)(b) will be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Section 20 – Prohibition of commercial dealings in parts of a human body for transplantation

55. 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).

56. 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.

57. 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).

58. 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 47, assist with obtaining tissue for transplantation in particular on a not-for-profit basis.

59. Subsection (4) sets out the penalties attaching to an offence under section 20(1). It 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 the statutory maximum, or both. On conviction on indictment, that person will be liable to imprisonment for a term not exceeding 3 years, to a fine, or both. Subsection (5) sets out the penalties attaching to an offence under sections 20(2). It provides that a person guilty of an offence under subsection (2) 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.

60. Subsection (6) provides definitions of the terms “advertisement” and “reward” used in section 20.

Section 21 – Summary proceedings for offences under sections 17, 19(4) or 20(2)

61. Section 21 provides that the time bar on commencing summary proceedings in relation to any of the offences under sections 17, 19(4) or 20(2) comes into operation 6 months after evidence sufficient to justify proceedings comes to the Lord Advocate’s knowledge.

22 - Authorisation for transplantation to have priority

62. The effect of section 22 is that authorisations under section 6(1) or 9(1) as respects removal and use of any part of a body to be used for transplantation which are in force immediately before a person's death, or any right of a person to authorise removal and use for transplantation of a part of a deceased person's body for transplantation under section 7(1), (2), (3), 11(1), (2), (3) or 12(1) take priority over authorisation, or the right to give authorisation, as respects the use of the body for a post mortem examination or requests by a person that their body be used for anatomical examination.

PART 2: POST-MORTEM EXAMINATIONS

Section 23 – Meaning of post-mortem examination for purposes of Act

63. Section 23 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 24 – Disapplication of sections 23 and 27 to 37 as respects procurator fiscal

64. Section 24 provides that none of the relevant provisions Part 2 of the Act (sections 23 and 27 to 37) affect anything done for the purposes of the functions, or under the authority of, the procurator fiscal. These provisions apply therefore only in relation to post-mortem examinations as defined in section 23 (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 25 – Disapplication of sections 27 to 35 and 37: bodies of persons dead for at least 100 years

65. Section 25 provides that sections 27 to 35 and section 37 do not apply in relation to a post-mortem examination of a body of a person who died at least 100 years before the day on which section 27 comes into force.

Section 26 – Consent by procurator fiscal to post-mortem examination

66. Subsection (1) 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. Subsection (2) provides that for the purposes of subsection (1) the fiscal may give consent verbally, provided it is confirmed in writing as soon as is reasonably practicable.

Section 27 – Requirements for carrying out post-mortem examination

67. This section provides that a hospital post-mortem examination cannot be carried out unless it has been duly authorised in accordance with section 29, 30, 31, 32 or 33 and the further requirements in relation to post-mortem examination and removal and retention of organs under section 35 are satisfied.

Section 28 – Removal during examination and retention of organs and other parts of a body

68. Section 26(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.)

69. 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 section 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 under the relevant section of the Act.

70. Subsection (3) provides that any part of the body of a deceased person (other than an organ) which is duly removed during a post-mortem examination by virtue of authorisation under the relevant section of the Act 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 29 – Authorisation of post-mortem examination etc.: adult

71. 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 28(2)(a) (audit, education, training or research).

72. Subsection (2) provides that such an authorisation under subsection (1) must be in writing and signed, or expressed verbally by the adult. If expressed verbally, this must be done in the presence of 2 witnesses.

73. Subsection (3) provides that a written authorisation may be withdrawn by the adult provided that it is withdrawn in writing, signed by the adult, and that a verbal authorisation may

be withdrawn by the adult either in writing and signed by the adult, or verbally by the adult in the presence of 2 witnesses.

74. Subsection (4) provides that if an adult is blind or unable to write, another adult can sign a written withdrawal of authorisation on their behalf in the presence of one witness.

75. Subsection (5) provides that a withdrawal of authorisation which is signed by a signatory on behalf of an adult who is blind or unable to write, must contain a statement, signed by the signatory and the witness in the presence of each other, which states that the adult expressed the intention to withdraw the authorisation and requested the signatory to sign the withdrawal on their behalf.

76. Subsection (6) provides that nothing in subsection (4) prevents an adult who is blind from withdrawing authorisation for a post-mortem examination and/ or removal, retention and use of an organ, in accordance with paragraph (a) of subsection (3).

Section 30 – Authorisation of post-mortem examination etc by adult’s nominee or nearest relative

77. Section 30(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 28(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 examination on the adult and the removal and retention of organs for one of the specified purposes.

78. 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 provide authorisation as if there were no such nomination in place.

79. Subsection (4) provides that authorisation by a nominated person must be in writing and signed by the nominated person 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 by the nearest relative and witnessed by one other person. Subsection (6) provides that in providing authorisation under subsections (1) or (2), 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.

80. Subsections (7) and (8) provide that authorisation can be withdrawn by the nominated person or nearest relative in writing, signed by the nominated person or nearest relative 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 31 – Authorisation of post-mortem examination etc.: child 12 years of age or over

81. 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 28(2)(a) (audit, education, training or research).

82. 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. Alternatively, if the child is blind or unable to write, such authorisation and the withdrawal of such authorisation may be signed by an adult on the child's behalf and witnessed by one witness. Subsection (3) provides that where a signatory signs authorisation or withdraws authorisation on behalf of a child the authorisation or withdrawal must contain a statement signed by the adult and the witness that the child expressed the intention to either give or withdraw the authorisation and requested the adult to sign on his or her behalf. Subsections (4) and (6) provide that any such authorisation on behalf of a child who is 12 years of age or over who is blind or unable to write must contain or be accompanied by certification from both the signatory and the witness that in their opinion the child understands the effect of the authorisation and is not acting under undue influence in giving it. A similar certification is required from both witnesses to an authorisation which is signed by the child himself or herself under subsection (2). Subsection (5) provides that nothing in the provisions in subsection (2) dealing with authorisation or withdrawal signed by a signatory on the child's behalf prevents a child who is blind from giving or withdrawing authorisation without such a signatory under subsection (2).

Section 32 – 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

83. 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 28(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 or a representative in place, a person who immediately before the death of the child had parental rights and responsibilities in relation to the child (but who is not a local authority) can give authorisation for a post-mortem examination on the child and the removal and retention of organs for one of the specified purposes.

84. 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 provide authorisation as if there were no such nomination in place.

85. Subsection (4) provides that authorisation by a child's nominee must be in writing, signed by the nominee 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 by the person and witnessed by 2 witnesses.

86. Subsection (6) provides that in providing authorisation under subsection (1) or (2) 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.

87. Subsections (7) and (8) provide that authorisation can be withdrawn by the nominated person or person with parental rights and responsibilities in writing, signed by the person 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 33 – Authorisation of post-mortem examination etc as respects child under 12 years of age

88. Section 33 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 (but who is not a local authority) 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 28(2)(a) (audit, education, training or research).

89. 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 by the person and witnessed by 2 witnesses. Authorisation may be subsequently withdrawn in writing, signed by the person who gave the authorisation and witnessed by one witness.

Section 34 – Nomination of person under section 30(1) or 32(1): additional provisions

90. Subsection (1) sets out the additional formalities relating to the appointment of a nominee by an adult under section 30(1) (authorisation of post-mortem examination etc, by adult's nominee) or by a child 12 years of age or over under section 32(1) (authorisation of post-mortem examination etc as respects child 12 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.

91. Subsection (2) provides that a witness to a nomination by an adult under section 30(1) or by a child under 22(1) must at the time of witnessing certify that in their opinion, the adult or child understands the effect of the nomination and is not acting under undue influence in giving it.

92. Subsection (3) provides that a person nominated by an adult under section 30(1) or by a child 12 years of age or over in terms of section 32(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.

93. Subsection (4) 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 35 – Post-mortem examination and removal and retention of organs: further requirements

94. 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 28(2)(a) (audit, education, training or research) unless they have satisfied themselves that it has been duly authorised in accordance with the relevant section and, as regards the carrying out of the examination, the consent of the procurator fiscal has been given where required.

95. 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.

96. Paragraph (a) applies to both written and verbal authorisations under Part 2 of the Act. Paragraphs (b), (d), (e), (g) and (h) all relate to written authorisations under various provisions in Part 2. Paragraph (f) relates to written authorisation which has been signed by an adult under section 31(1) on behalf of a child who is 12 years of age or over and who is blind or unable to write. 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 37, an offence will be committed if the activity is not authorised by the relevant provision in Part 2.

97. Paragraph (c) relates to verbal authorisation by an adult under section 29(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 29(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 by the adult 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 36 – Organ or tissue sample removed before day on which section 27 comes into force

98. Section 36 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 27 coming into force and held immediately before that day for any purpose set out in section 23(a) to (d) can continue to be retained and used for any or all of those purposes. The examination in question must, however, have had the characteristics of a post-mortem examination under the Act.

Section 37 – Offences: post-mortem examinations

99. Subsection (1) provides that a person commits an offence if that person carries out a post-mortem examination which has not been authorised in accordance with section 29, 30, 31, 32 or as the case may be 33, or removes or retains an organ at post-mortem examination without that removal or retention having been authorised in accordance with one of those provisions. It is a defence under subsection (2) 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 the activity to have been duly authorised in accordance with the relevant section under Part 2 of the Act.

100. 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 the statutory maximum or both. On conviction on indictment, that person will be liable to imprisonment for a term not exceeding 3 years, to a fine, or both.

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

Section 38 – Tissue sample becoming part of medical records of deceased person

101. Section 38 provides, in relation to examinations carried out for the purposes of the functions or under the authority of the procurator fiscal on or after the day this section 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 41) receives written notice from the fiscal that the sample is no longer required for the purposes of the functions of the fiscal.

Section 39 – Use of tissue sample which has become part of deceased's medical records

102. Section 39 provides that where, as a result of receipt of notice under section 38, a tissue sample has become part of the deceased's medical records, it can be used for specified purposes related to diagnosis and audit without authorisation, and for purposes of education, training or research with appropriate authorisation under Part 3, in accordance with section 42, 43, 44, 45 or as the case may be, 46.

Section 40 – Use of organ no longer required for procurator fiscal purposes

103. Section 40 provides, in relation to examinations carried out for the purposes of the functions or under the authority of the procurator fiscal on or after the day this section 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 41 – Notice under section 38(2) or 40(2)(a): further provisions

104. Section 41 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 38(2) or 40(2)(a).

Section 42 – Authorisation of use etc after examination: adult

105. Section 42(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 was removed but 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. 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. Alternatively, if the adult is blind or unable to write, such authorisation and the withdrawal of such authorisation may be signed by another adult on behalf of the adult who is blind or unable to write. If it is so signed it must be witnessed by one witness. Subsection (3) provides that where a signatory signs authorisation or withdraws authorisation on behalf of an adult in this way, the authorisation or withdrawal must contain a statement signed by the signatory and the witness that the adult expressed the intention to either give or withdraw the authorisation and requested the signatory to sign on his or her behalf. Subsection (4) provides that nothing in the provisions in subsection (2) dealing with authorisation or withdrawal signed by a signatory on the adult's behalf prevents an adult who is blind from giving or withdrawing authorisation without such a signatory under subsection (2).

Section 43 – Authorisation of use etc after examination: adult's nearest relative

106. Section 43(1) provides that where no authorisation by the adult of any of the matters referred to in section 42(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 39(b)).

107. Subsections (2) and (3) provide that such authorisation by the nearest relative must be in writing, signed by the nearest relative and witnessed by one witness. The authorisation 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 44 – Authorisation of use etc after examination: child 12 years of age or over

108. Section 44(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 was removed but 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. 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. Alternatively, if the child is blind or unable to write, such authorisation and the withdrawal of such authorisation may be signed on behalf of the child. If it is so signed it must be witnessed by one witness. Subsection (3) provides that where a signatory signs authorisation or withdraws authorisation on behalf of a child in this way, the authorisation or withdrawal must contain a statement signed by the signatory and the witness that the child expressed the intention to either give or withdraw the authorisation and requested the signatory to sign on his or her behalf. Subsections (4) and (6) provide that any such authorisation on behalf of a child who is 12 years of age or over who is blind or unable to write must contain or be accompanied by certification from both the signatory and the witness that in their opinion the child understands the effect of the authorisation and is not acting under undue influence in giving it. A similar certification is required from both witnesses to an authorisation which is signed by the child himself or herself under subsection (2). Subsection (5) provides that nothing in the provisions in subsection (2) dealing with authorisation or withdrawal signed by a signatory on the child's behalf prevents a child who is blind from giving or withdrawing authorisation without such a signatory under subsection (2).

Section 45 – Authorisation of use etc after examination: person with parental rights and responsibilities for child 12 years of age or over

109. Section 45(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 44(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 (but who is not a local authority) may authorise one or more of those matters. Authorisation is needed where the use relates to the purposes of education, training or research.

110. 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, signed by the person who gave the 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 46 – Authorisation of use etc after examination: person with parental rights and responsibilities for child under 12 years of age

111. Section 46(1) provides that where a child dies under 12 years of age, authorisation of one or more of the matters referred to in section 44(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 (but who is not a local authority). Authorisation is needed where the use relates to the purposes of education, training or research. 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 47 – Use of tissue sample removed before day on which section 38 comes into force

112. Section 47 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 section 38 comes into force and held immediately before that day for use for any of the purposes set out in section 39(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 48 – Use of organ removed before day on which section 40 comes into force

113. Section 48 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 section 40 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).

114. 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 40) 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 40) 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 49 – Conditions attached to authorisation

115. Paragraph (a) of subsection (1) provides that conditions can be attached to the following authorisations under Part 1 of the Act: an authorisation by the nearest relative of an adult under section 7(1); an authorisation under section 9(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 10(1) by a person who immediately before the death of a child who died under 12 years of age had parental rights and responsibilities in relation to that child. However, conditions can only be attached to authorisation by virtue of those provisions where the removal and use of a body part is for the purposes of research, education, training or audit. Conditions cannot be attached to such authorisation when removal and use of a body part is for the purpose of transplantation.

116. Section 49(1) also provides that conditions can be attached to the following authorisations under Parts 2 and 3: authorisation by a nominee of an adult under section 30(1) or the nominee of a child who died 12 years of age or over under section 32(1); an authorisation by

the nearest relative of an adult under section 30(2) or 43(1); an authorisation under section 32(2) or 45(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 33(1) or 46(1) by a person who immediately before the death of a child who died under 12 years of age had parental rights and responsibilities in relation to that child.

117. 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 forms that will be prescribed for hospital post-mortem examinations will allow for the making of such conditions.

Section 50 – Nearest relative

118. Section 50 sets out the arrangements for determining the person's nearest relative, who may provide 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 30 (Part 2). Subsection (2) provides that, in relation to authorisation by the nearest relative of a deceased adult under section 43 (Part 3) in the context of tissue sample 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) prevents an adult's spouse or civil partner from being able to give authorisation in terms of the nearest relative hierarchy if they are permanently separated or have deserted, or been deserted by, their partner at the time their partner dies. Subsection (4) provides that the relationships listed in the different paragraphs of subsection (1) rank in the order of those paragraphs. Subsection (5) provides that relatives at the same level in the nearest relative hierarchy in subsection (1) will have the same equal status in terms of giving authorisation under sections 7, 30 or 43. Subsection (6) sets out the circumstances in which a person's relationship with the deceased adult is to be left out of account.

Section 51 – Witnesses: additional provisions

119. Section 51(1) provides for additional requirements which must be satisfied in relation to the witnessing of authorisation, withdrawal of authorisation, nomination or withdrawal of nomination in writing, in terms of the provisions specified in this subsection. The specified provisions include those which allow a signatory to sign on behalf of an adult or a child 12 years of age or over who is blind or unable to write. The requirements are that a witness must be an adult, must be a witness to the signature and the content of the writing and must sign the writing. Where 2 witnesses are required they must be present at the same time. Subsection (2) provides for additional requirements in relation to the witnessing of verbal authorisation or verbal withdrawal of authorisation by an adult in terms of section 29(2)(b) and (3)(b)(ii). The requirements are that each of the 2 witnesses must be an adult and must be a witness to the verbal expression of authorisation or withdrawal. Again, both witnesses must also be present at the same time.

Section 52 – Power to prescribe forms and descriptions of persons who may act as a witness

120. Section 52 gives the Scottish Ministers power to prescribe by regulations the form in which authorisations by nominees or nearest relatives is to be, or may be given, and the type of people who can act as witnesses in certain cases.

PART 5: AMENDMENT OF THE ANATOMY ACT 1984

Section 53 – Amendment of the Anatomy Act 1984

121. Section 53 of the Act 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.

122. Subsection (2) amends section 1 (definitions and scope) of the 1984 Act. Paragraph (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. Paragraph (b) makes clear that an imported body is not to be treated as an anatomical specimen until authority for its anatomical examination has been given. In doing so it will ensure that where a body is imported for use for anatomical examination in Scotland it is not regarded as an anatomical specimen as defined in the Anatomy Act 1984 until authority for the examination of that body in Scotland has been given. Paragraph (c) 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 Act) from the scope of the 1984 Act. Paragraph (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 Act, the Act, 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.

123. 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 of cause of death 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.

124. 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.

125. 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 (1A) to (1D) into section 4 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 must 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(1C) provides for additional requirements in respect of requests by persons aged 12 years or over, but not yet an adult, including requests from such persons who are blind or unable to write. Requests from persons aged 12 years or over, but not yet an adult will require to be witnessed by two adults, present at the same time, and each witness must certify in writing that the person understood the effect of the request and was not acting under undue influence in making it. For requests from such persons who are blind or unable to write the signatory and the witness must certify in writing that the person understood the effect of the request and was not acting under undue influence in making it. 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).

126. 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 (ca) maintains the restrictions that authorisation for anatomical examination cannot be given by a person entrusted with a body for the purpose only of its interment or cremation and that authority for lawful examination expires at the end of the statutory period. 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 Act 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.

127. 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 must be licensed under the Act to carry out anatomical examinations and to have possession of anatomical specimens, and who is lawfully in possession of an imported body outwith Scotland 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. If authority under section 4A is given, the anatomical examination of the imported body is lawful provided that the requirements in new section 4B(1) and (2), which also apply to the anatomical examination in accordance with a request under section 4, are met. 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 the setting of, and expiry of, the statutory period of 3 years, after which the authority to use a body for anatomical examination expires.

128. Subsection (7) amends section 5(1), (2), (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 under section 4A has expired or situations where a body has been used for anatomical examination outwith Scotland, other than the case where the body has been imported for use for, and may be used or is being used for, anatomical examination in 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 (aa) provides that the prohibition on any person having a body or part of a body that section 5(1) applies to, does not apply where it is permitted in the circumstances set out in new subsection (4A). 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 in certain circumstances to have possession of part of an imported body whose anatomical examination has been concluded. Paragraph (b) also inserts a new subsection (4A) which allows, in certain circumstances, the possession 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 bodies and parts of bodies in the interests of training, as well as in the interests of education or research.

129. Subsection (8)(a) adjusts section 6(1) of the Anatomy Act 1984 to reflect the proposed change to a procedure of only accepting written requests, with special arrangements for those

who are blind or unable to write. Paragraph (b) 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.

130. 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 (1A) of new section 6A exempts persons responsible for the operation or control of museums, which Scottish Ministers specify by order, from the licensing requirements for the public display of bodies and body parts. Subsections (2), (2A), (2B), (2C), (2D) and (2E) allow public display of anatomical human remains, subject to conditions. The substituted subsections allow, in defined conditions, the public display of the following: parts from bodies retained after anatomical examination in Scotland has concluded (subsections (2) and (2A)); bodies and parts that are in the course of being used for anatomical examination in Scotland (subsections (2B) and (2C)); parts of bodies used outwith Scotland for anatomical examination or examination which has the characteristics of anatomical examination during the course of which the part was removed (subsection (2D)); bodies used outwith Scotland for anatomical examination or examination which has the characteristics of anatomical examination but which have not been anatomically examined in Scotland (subsection (2E)). Subsection (3) of the new section 6A allows Scottish Ministers to grant a licence to a person to display a body or body part if they think it desirable to do so in the interests of education, training or research. A person will be authorised to publicly display a body or body part under section 6A(3), if at the time of the display, he is so licensed. Subsections (3A) and (3B) of the new section 6A prohibits the public display of bodies or part of bodies during while a procedure in relation to an anatomical examination or any similar procedure is actually being carried out. This prohibition applies to persons who are authorised to publicly display the body or part under a licence from the Scottish Ministers and to persons responsible for the operation or control of museums specified in an order by the Scottish Ministers, and so exempt from the requirement to be 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 excludes from the prohibition on public display, 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 an order specifying the persons responsible for the operation or control of museums, which will not require a licence for the public display of human anatomical remains, and regulations under inserted section 6A(4) shall be subject to negative procedure in the Scottish Parliament.

131. 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.

132. 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.

133. 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 applied to bodies and 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 bodies and 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.

134. 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 bodies and parts of a body, and those authorised under section 6A(3) to publicly display parts of bodies and 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 bodies or parts of a body) or under section 6A(3) (to publicly display bodies or parts of a body).

135. 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.

136. 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.

137. 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(1) of the 1984 Act, and the display a body or part of a body in contravention of new subsection (3A), 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 a body or 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.

138. 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 54 – Arrangements by Scottish Ministers for assistance with functions under sections 1, 2, 17(3), (4) or (5), 18, 19(2), or 20(3)

139. Section 54 provides that the Scottish Ministers may make arrangements with other UK public authorities to undertake, or assist them in relation to, any of their functions under sections 1, 2, 17(3), (4) or (5) (except the power to make regulations under that section), 18 (except the power to make regulations under that section), 19(2) or 20(3). This would allow the Scottish Ministers to have certain functions carried out by an organisation such as the Human Tissue Authority.

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

Section 55 – Power to give effect to Community obligations

141. Section 55 gives the Scottish Ministers power to amend the Act 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 56 – Bodies corporate etc.

142. Section 56 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.

Section 57 – Amendment of the Adults with Incapacity (Scotland) Act 2000

143. This provision will ensure that a welfare attorney or welfare guardian does not have powers under the Adults with Incapacity Act 2000 to make any requests on behalf of an adult under the Anatomy Act 1984, to give any authorisation on behalf of an adult for transplantation, hospital post-mortem or retention of organs or tissues from fiscal post mortem, or to make any nomination on behalf of the adult for a hospital post mortem. The intention in relation to authorisations for the post-death situation is to put beyond doubt that welfare attorneys and welfare guardians do not have powers under the 2000 Act to authorise on behalf of the adult (for example, to sign a kidney donor card for the adult). In relation to live transplants authorised under the Act, the intention is that these types of donation (organs in the context of a domino organ transplant operation and regenerative tissue) are to be considered instead under the procedures being set up by the Human Tissue Authority.

PART 7: GENERAL

Section 58 – Ancillary provisions

144. Section 58 enables the Scottish Ministers to make further provision, by order, which is incidental to or consequent on the Act and to allow transitional or savings provisions as required in implementing the Act's provisions.

Section 59 – Regulations or orders

145. Subsection (1) provides that powers to make orders or regulations in the Act 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 55, an order under section 58 which contains provisions which alter the text of an Act and regulations under section 17(3), (4) or (5) are to be the subject of affirmative resolution.

Section 60 – Interpretation

146. Section 60 defines terms used throughout the Act.

Section 61 – Repeals

147. Section 61 introduces schedule 1 (which contains consequential repeals).

Section 62 – Short title and commencement

148. This section provides for the short title of the Act. Further, section 62 allows the Scottish Ministers to bring the provisions of the Act (except sections 52, 59, 60 and 62) into force by order and to set different dates to commence different provisions. The section provides for sections 52, 59, 60 and 62 to come into force on Royal Assent.

PARLIAMENTARY HISTORY

The following table sets out, for each Stage of the proceedings in the Scottish Parliament on the Act for this Act, the dates on which the proceedings at that Stage took place, the references to the Official Report of those proceedings and the dates on which Committee Reports and other papers relating to the Act were published, and references to those Reports and other papers.

Proceedings and Reports	Reference
Introduction	
3 June 2005	<u>Act as Introduced (SP Act 42)</u>
17 th Meeting 2005 (Session 2) – Preliminary Discussion	<u>7 June, Col 2019 & Minutes</u>
Stage 1	
<i>(a) Health Committee</i>	
19 th Meeting 2005 (Session 2)	<u>21 June Col 2086 & Minutes</u>
20 th Meeting 2005 (Session 2)	<u>8 Sep Cols 2091 - 2112 & Minutes</u>
21 st Meeting 2005 (Session 2)	<u>13 Sep Cols 2128 - 2164 & Minutes</u>
23 rd Meeting 2005 (Session 2)	<u>27 Sep Cols 2223 - 2256 & Minutes</u>
24 th Meeting 2005 (Session 2)	<u>3 Oct Cols 2261 - 2281 & Minutes</u>
25 th meeting 2005 (Session 2)	<u>25 Oct Cols 2301 - 2327 & Minutes</u>
22 November 2005: 19th Report 2005 (Session 2): Stage 1 Report on Human Tissue (Scotland) Act	<u>Stage 1 Report</u>
<i>(b) Subordinate Legislation Committee</i>	<u>25 Oct Cols 1239 - 1243 & Minutes</u>
28 th Meeting 2005 (Session 2)	<u>25 Oct Col 1239 - 1243 & Minutes</u>
29 th Meeting 2005 (Session 2)	<u>1 Nov Cols 1278 - 1281 & Minutes</u>
<i>(c) Finance Committee</i>	
18th Meeting 2005 (Session 2)	<u>8 Sep Cols 2746 - 2747 & Minutes</u>
<i>(d) Consideration by Parliament</i>	
Stage 1 debate 30 November 2005	<u>30 Nov Cols 21232 - 21279</u>

*This document relates to the Human Tissue (Scotland) Act 2006 (asp.4)
which received Royal Assent on 16 March 2006*

Stage 2	
<i>(a) Health Committee</i>	
32nd Meeting 2005 (Session 2)	<u>20 December 2005, Cols 2431 - 2458 & Minutes</u>
2nd Meeting 2006 (Session 2)	<u>17 January 2006, Cols 2475 - 2492 & Minutes</u>
Act (as Amended at Stage 2)	<u>Act as amended (SP 42A)</u>
Stage 3	
<i>Consideration by Parliament</i>	
Stage 3 debate, 2 February 2006	<u>2 February 2006, Cols 22960 - 23007</u>
Act passed, 2 February 2006	<u>Act as passed (SP Act 42B)</u>
Royal Assent	
16 March 2006	<u>Human Tissue (Scotland) Act 2006 (asp4)</u>

*This document relates to the Human Tissue (Scotland) Act 2006 (asp.4)
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HUMAN TISSUE (SCOTLAND) ACT
[AS AMENDED AT STAGE 2]

REVISED EXPLANATORY NOTES

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