MEMORANDUM ON DELEGATED POWERS
HUMAN TISSUE (SCOTLAND) BILL

Purpose

1. This memorandum, which is required by Rule 9.4A of the Parliament’s Standing Orders, has been prepared by the Scottish Executive to assist consideration by the Subordinate Legislation Committee, in accordance with Rule 9.6.2 of the Standing Orders, of the provisions of the Human Tissue (Scotland) Bill conferring power to make subordinate legislation. It describes the purpose of each such provision and explains why the matter is to be left to subordinate legislation. The following paragraphs outline the main provisions of the Bill. This memorandum should be read in conjunction with the Explanatory Notes, Policy Memorandum and Financial Memorandum for the Bill.

Outline of the Bill

2. This Bill deals with the removal and use of body parts in a number of circumstances. In particular, it makes provision in relation to transplantation from dead and living donors; removal of parts from a deceased person’s body and use of those body parts for the purposes of research, education or training, or audit; the carrying out of a post-mortem examination, the removal of parts from a deceased person’s body during such an examination and retention and use thereafter for the purposes of the post-mortem examination or for the purposes of research, education or training, or audit; use of certain body parts removed during an examination of a body for the purposes of the functions, or under the authority of the procurator fiscal and no longer needed for fiscal purposes; regulation of anatomical examinations and public display of an anatomical specimen or a body or part of a body which has been used for anatomical examination. While the activities regulated mainly relate to dead bodies, the Bill also regulates transplants from living donors.

Parts of the Bill

3. The Bill is divided into seven Parts which deal with the following proposed measures:

Part 1: Transplantation etc.

Part 1 of the Bill gives the Scottish Ministers duties and powers in relation to transplantation of parts of a human body. It regulates the removal and use of parts of the body of a deceased person for the purposes of transplantation, research, education or training or audit and, in particular, provides for a system of authorisation in relation to such activities. It also makes provision in relation to the preservation of body parts for transplantation and transplants involving live donors and prohibits commercial dealing in human body parts for transplantation.

Part 2: Post-Mortem Examinations

Part 2 regulates the carrying out of a post-mortem examination which is not instructed by the Procurator Fiscal and the removal and use of parts of a human body during such a post-mortem examination. Such activities are subject to a system of authorisation. Part 2 also makes provision in relation to organs or tissue sample removed from a body during an examination having the characteristics of a post-mortem examination, which was carried out before the requirements under Part 2 come into force. It enables such organs and tissue
sample which were held immediately before that day for use for certain purposes to be retained and used on and after that day for those purposes without authorisation.

**Part 3: Tissue Sample or Organs No Longer Required for Procurator Fiscal Purposes**

Part 3 of the Bill provides a means by which tissue sample and organs removed from the body of a deceased person during an examination of the body for the purposes of the functions, or under the authority of the procurator fiscal, and which are no longer required for the fiscal’s purposes, to be retained and used for similar purposes to those for which body parts removed during a hospital post-mortem examination may be used. It also regulates the use for such purposes of tissue sample and organs removed from the body of a deceased person during an examination of the body for the purposes of the functions, or under the authority of the fiscal which is carried out before certain provisions of the Bill come into force.

**Part 4: Supplementary Provision**

Part 4 contains provisions supplementary to Parts 1 to 3.

**Part 5: Amendment of the Anatomy Act 1984**

Part 5 of the Bill amends the Anatomy Act 1984 which regulates the use of bodies of deceased persons and parts of such bodies for anatomical examination. It extends the meaning of anatomical examination and the regulatory requirements to bodies and body parts which are imported for use for anatomical examination in Scotland. It also prohibits the public display of anatomical specimens, bodies or body parts except in specified circumstances and generally amends the regulatory process under the 1984 Act by, for example, introducing a right of appeal against licensing decisions made under the 1984 Act by Scottish Ministers and providing that Scottish Ministers may prepare a code of practice relating to activities referred to in the Act.

**Part 6: Miscellaneous**

Part 6 contains a number of miscellaneous provisions related to earlier parts of the Bill. It gives the Scottish Ministers power to make arrangements with a public authority in the UK for assistance with the Ministers’ functions under certain provisions of the Bill. It gives the Scottish Ministers powers by regulations to amend the Act which the Bill will become for the purposes of implementing any Community obligation of the UK relating to material which consists of, includes or is derived from human cells and dealing with matters arising out of or related to such an obligation.

**Part 7: General**

Part 7 contains a number of general provisions related to earlier parts of the Bill. It gives the Scottish Ministers powers by order to make further provision which is incidental to or consequent on the Bill and to allow transitional or savings provisions as required in implementing the Bill’s provisions.
Delegated Powers

4. The Bill confers powers on the Scottish Ministers to make orders and regulations in relation to a range of matters dealt with in the Bill. Some of the powers contained in the Bill are new, while others replace or update existing powers in the Human Tissue Act 1961, the Human Organ Transplants Act 1989 and the Anatomy Act 1984.

5. Section 56(2) of the Bill confers power on the Scottish Ministers to make the necessary commencement order. As this is a commencement provision there is no parliamentary procedure.

6. This Memorandum describes provisions of the Human Tissue (Scotland) Bill which confer power to make subordinate legislation. It sets out:

- the persons upon whom, or the body upon which, power to make subordinate legislation is conferred and the form in which the power is to be exercised;
- why it is considered appropriate to delegate the power to subordinate legislation and the purpose of each such provision;
- the Parliamentary procedure to which the exercise of the power to make subordinate legislation is to be subject, if any.

7. In deciding whether to adopt negative or affirmative resolution procedure, careful consideration has been given to the degree of parliamentary scrutiny that is felt to be required for the regulations, balancing the need for the appropriate level of scrutiny with the need to avoid using up parliamentary time unnecessarily. Affirmative procedure is used where the order or regulation making powers allow for the modification of any enactment or where there is significant public interest. Negative resolution procedure is used otherwise.

Part 1: Transplantation etc.

Relevant provision: Section 12(1)(b)

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

8. Section 12(1)(b) of the Bill gives Scottish Ministers powers to make regulations to provide for the persons who may be authorised to remove a part of the body of a deceased person for the purposes of transplantation, research, education or training or audit. Section 12(2) provides that such regulations may in particular provide for a registered medical practitioner to authorise the carrying out of the removal by a person who is not a registered medical practitioner. The intention is that the person authorised to carry out the removal of body parts will be someone who has been trained to do so but who may not be a registered medical practitioner. The regulations will make detailed provision as to which person will satisfy these requirements and how the authorisation process will work in practice. It is considered appropriate to confine this sort of detail to subordinate legislation rather than primary legislation because it may be necessary over time to change the requirements as to who may be an authorised person under this provision. This provision is subject to negative
procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Relevant provision: Section 15(3)

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

9. **Section 15(3)** of the Bill gives the Scottish Ministers powers by regulations to provide that no offence is committed under section 15(1)(b) (in relation to 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 under section 15(2)(b) (in relation to use for transplantation an organ or part of an organ which has come from the body of a living adult) where the requirements of section 15(3) are met.

10. The requirements are that the Scottish Ministers must be satisfied that no reward has been or will be given in contravention of the provisions of section 17 (prohibition of commercial dealings in parts of a human body for transplantation) and that such other requirements or conditions as may be specified in the regulations are complied with. Where regulations provide for such an exception from the offence provisions in section 15(1)(b) or 15(2)(b), it is sufficient if the person reasonably believes that the exception applies (section 15(5)). Section 15(4) provides that regulations under section 15(3) must include provision as to appeals against decisions made in relation to matters which fall to be decided under the regulations.

11. Again, it is considered to be more appropriate for detailed provisions to be confined to subordinate legislation as requirements or conditions may change over time. The current requirements and conditions are set out in the Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI 1989 No. 2480), and it is likely that these will in general be carried forward in the regulations made under section 15(3). The conditions in particular deal with a number of detailed and sensitive issues which could well require modification to take account of changing circumstances and practice. It is also important that the requirements and conditions should maintain consistency with the relevant Regulations and statutory Code of Practice made under the equivalent provisions (sections 26(2)(h) and 33(3)) of the Human Tissue Act 2004 (c.30). The regulations will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Relevant provision: Section 16(1)

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

12. **Section 16(1)(a)** of the Bill gives the Scottish Ministers powers to make regulations requiring such persons (or descriptions of persons) as may be specified in the regulations, to maintain records in connection with the removal of parts from human bodies for transplantation and the use or retention of parts removed from bodies of deceased persons for the purposes of research, education or training or audit; Section 16(1)(b) gives Scottish
Ministers powers to make regulations requiring such persons (or descriptions of persons) as may be specified in the regulations to make specified information available to the Scottish Ministers or to a specified authority with respect to such matters.

13. Under section 16(2), the Scottish Ministers must keep a record of the information provided to them in terms of regulations made under subsection (1). Similarly, under section 16(3), any authority specified in the regulations must keep a record of the information provided to it in pursuance of the regulations. Section 16(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.

14. Again, it is considered to be more appropriate for detailed provisions to be confined to subordinate legislation as the persons who may maintain such records or provide such information (or any specified authority to which information is to be provided) may change over time. The regulations will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Part 3: Tissue sample or organs no longer required for procurator fiscal purposes

Relevant Provision: Section 35(2)(c)

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

15. Section 35(2)(c) of the Bill gives the Scottish Ministers the power to specify by order such person (or persons) or group (or groups) of persons who may provide approval to carry out research on an organ removed from the body of a deceased person during an examination of the body carried out for the purposes of the functions or under the authority of the procurator fiscal after the new legislation comes into force and which is no longer required for the purposes of the functions of the fiscal. The intention is that the order will specify that a Research Ethics Committee will be able to provide such approval, in order to provide a safeguard against research being carried out on such organs for undesirable purposes.

16. Again, it is considered to be more appropriate for these provisions to be confined to subordinate legislation as the persons or groups who may undertake the regulatory role currently undertaken by the Research Ethics Committee may change over time. The order will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Relevant Provision: Section 36(2)(c)

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

17. Section 36(2)(c) of the Bill gives the Scottish Ministers powers to specify by order the person or holder of a post who is defined as the “manager of an establishment” in an establishment other than a health service hospital or a university for the purposes of sections 33(2) and 35(2)(a). In terms of those sections, the “manager of an establishment” is the person who has received written notification from the procurator fiscal that an organ or tissue
removed from the body of a deceased person is no longer required for fiscal purposes and can therefore be used for specified purposes.

18. Again, it is considered to be more appropriate for these provisions to be confined to subordinate legislation as the establishments in which such activities may be undertaken may change over time. The order will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

**Relevant Provision: Section 43(2)**

- **Power conferred on:** The Scottish Ministers
- **Power exercisable by:** Order made by Statutory Instrument
- **Parliamentary procedure:** Negative resolution procedure

19. **Section 43(2)** of the Bill gives the Scottish Ministers powers to make an order to specify such person (or persons) or group (or groups) of persons who may carry out either “existing approved research”, that is research approved before the new legislation comes into force, or “new approved research” which is research approved on or after the day on which section 35 of the Bill (removal and use of an organ no longer required for procurator fiscal purposes) comes into force. The intention is that the order will specify that such research is to be approved by a Research Ethics Committee in order to provide a safeguard against research being carried out on such organs for undesirable purposes.

20. Again, it is considered to be more appropriate for these provisions to be confined to subordinate legislation as the persons or groups who may undertake the regulatory role currently undertaken by the Research Ethics Committee may change over time. The Order will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

**Part 4: Parts 1 to 3 Supplementary Provision**

**Relevant Provision: Section 47**

- **Power conferred on:** The Scottish Ministers
- **Power exercisable by:** Regulations made by Statutory Instrument
- **Parliamentary procedure:** Negative resolution procedure

21. **Section 47(a)** of the Bill gives the Scottish Ministers powers to prescribe by regulations the form in which authorisation for certain activities under Parts 2 and 3 of the Bill can be given by nominees, nearest relatives or persons with parental rights and responsibilities in relation to a child. Section 47(b) gives Scottish Ministers powers to prescribe by regulations descriptions of persons who are eligible to act as witnesses to authorisation in certain cases.

22. Subordinate legislation is considered more appropriate for this sort of detail than primary legislation. This is especially the case here as the forms in which authorisation may be provided may require to be updated from time to time. The regulations will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.
Part 5: Amendment of the Anatomy Act 1984

Relevant Provision: Section 48(6) new section 4B(3) of the 1984 Act

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

23. Section 48(6) of the Bill (new section 4B(3) of the 1984 Act) gives the Scottish Ministers the power to amend by order the statutory period of 3 years beginning with the date of the deceased’s death which governs the use of imported bodies for anatomical examination. This gives Scottish Ministers the same power as they already have governing the use of bodies for anatomical examination from the UK and seeks to create the same conditions for imported bodies as apply to bodies from the UK. The same statutory period of three years and the power to amend this period by order in relation to use of non-imported bodies is provided for in section 4(10) of the 1984 Act. The power is required to allow for the need to account for varying and at present unforeseen circumstances, around the availability and preservation of available bodies. If there was a shortage of available bodies, then Ministers may want to consider extending the period to, for example, 4 years.

24. It is considered appropriate to confine this to subordinate legislation to be consistent with the present arrangement for bodies from the UK. The order under this provision will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Relevant Provision: Section 48(9) new section 6A(4) of the 1984 Act

Power conferred on: The Scottish Ministers
Power exercisable by: Regulations made by Statutory Instrument
Parliamentary procedure: Negative resolution procedure

25. Section 48(9) of the Bill (new section 6A(4) of the 1984 Act) gives Scottish Ministers the power to specify the content of the records that must be kept by a person who has been granted a public display licence under new section 6A(3) of the 1984 Act. The need for a public display licence is a new provision which seeks to forbid the public display of anatomical specimens, bodies or body parts except in specified circumstances, including under a licence granted by Scottish Ministers. In the same way that other licence holders at present under the Act are required to keep appropriate records, it makes sense that public display licence holders should also keep appropriate records.

26. Subordinate legislation is considered more appropriate for the detail of the record keeping, which may require to be updated from time to time, and this is consistent with the present arrangements of record keeping by other licence holders (under section 3(5)(a) of the 1984 Act). The regulations under this provision will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.
Relevant Provision: Section 48(12)(a)

Power conferred on: The Scottish Ministers  
Power exercisable by: Regulations made by Statutory Instrument  
Parliamentary procedure: Negative resolution procedure

27. Section 48(12)(a) of the Bill amends existing regulation making powers under section 8 of the 1984 Act. Currently, under section 8(1)(a) of the 1984 Act, the regulation making power of the Scottish Ministers applies in relation to bodies the anatomical examination of which is lawful by virtue of section 4, with a view to securing their efficient and orderly examination and the decent disposal of bodies and body parts after their examination has been concluded. Section 48(12)(a) extends the scope of this regulation making power to include a reference new section 4A, which covers the lawful examination of imported bodies. This is necessary to ensure consistency of approach in relation to imported and non-imported bodies.

28. The existing regulation-making powers under section 8 of the 1984 Act are subject to negative resolution procedure.

Relevant Provision: Section 48(12)(b)

Power conferred on: The Scottish Ministers  
Power exercisable by: Regulations made by Statutory Instrument  
Parliamentary procedure: Negative resolution procedure

29. Section 48(12)(b) of the Bill also amends existing regulation making powers under section 8 of the 1984 Act. Currently, under section 8(1)(b) of the 1984 Act, the regulation making powers that exist with a view to securing that body parts are decently cared for apply in relation to body parts the possession of which is lawful by virtue of section 6 of the 1984 Act. Section 6 is a general provision relating to the lawful possession of body parts. Section 48(12)(b) changes the scope of this regulation making power so that it applies in relation to body parts the possession of which is authorised under section 5(5) of the 1984 Act. Section 5(5) makes provision for the process of authorisation of possession of body parts by licence where Scottish Ministers consider it desirable to grant such a licence in the interests of education or research. The effect therefore will be that the regulation making power that exists with a view to securing that body parts are decently cared for will be narrowed to cover those situations where a licence has already been granted in the interests of education or research.

Relevant Provision: Section 48(12)(c)

Power conferred on: The Scottish Ministers  
Power exercisable by: Regulations made by Statutory Instrument  
Parliamentary procedure: Negative resolution procedure

30. Section 48(12)(c) of the Bill also amends existing regulation making powers under section 8 of the 1984 Act. Section 48(12)(c) extends the scope of this regulation making power to include a reference new section 6A(3), which grant the Scottish Ministers powers to grant a licence to a person to publicly display a body part if Ministers think it desirable to do so in the interests of teaching or studying, or training in or researching into, the gross
structure of the human body. The purpose of this new section is to put controls in place, which do not exist at present, over the public display of bodies and body parts. Regulations under this provision are to be made with a view to securing that the body parts used for public display under new section 6A are decently cared for and displayed with appropriate respect. This is necessary to ensure consistency of approach in relation to body parts used for public display and body parts used for other purposes, i.e., anatomical examination in licensed premises, under the 1984 Act.

**Relevant Provision: Section 48(13) new section 8A(2)(a) and (b) of the 1984 Act**

- **Power conferred on:** The Scottish Ministers
- **Power exercisable by:** Order made by Statutory Instrument
- **Parliamentary procedure:** Negative resolution procedure

31. **Section 48(13)** of the Bill (new section 8A(2)(a) and (b) of the 1984 Act) gives Scottish Ministers the power to bring into effect a code of practice to give practical guidance and lay down standards for those who are licensed to carry out anatomical examinations and those who are licensed to publicly display a body or body part. There was an overwhelming response in the consultation to issuing a code of practice, which does not exist at present. A code of practice was seen as facilitating consistency of good practice, providing accessible and readily amended guidance, helping to maintain a consistent practice with the rest of the UK, providing help for license holders and reassurance to the public.

32. The detail of the code of practice will be informed by a consultation exercise with a variety of stakeholders including doctors, licensed teachers, professional bodies, the public and practitioners. In addition the Bill stipulates in section 48(13) (new section 8A(3)(b) of the 1984 Act) that Scottish Ministers will, before confirming the code of practice by order, lay a draft of the code before the Scottish Parliament.

33. The confirmation and bringing into force of the code of practice is considered to be a matter that it appropriate for subordinate legislation, to allow the detail of the code to be updated from time to time. The order under this provision will be subject to negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

**Part 6: Miscellaneous**

**Relevant Provision: Section 50(1)**

- **Power conferred on:** The Scottish Ministers
- **Power exercisable by:** Regulations made by Statutory Instrument
- **Parliamentary procedure:** Affirmative resolution procedure

34. **Section 50(1)** of the Bill gives the Scottish Ministers powers by regulations to amend the Act which the Bill will become for the purposes of implementing any Community obligation of the UK relating to material which consists of human cells. It is considered appropriate to provide for this power in subordinate legislation because Community obligations may change over time. Transposition of the EU Directive on the Safety of Tissue and Cells into domestic legislation by April 2006 is being taken forward on a UK basis by the 4 Health Departments and much of the detail is still under consideration. The regulations under this provision will be subject to affirmative procedure because the powers allow for amendment of the Act.
Part 7: General

Relevant Provision: Section 52(1)

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: Negative or affirmative resolution procedure

35. Section 52(1) of the Bill gives the Scottish Ministers powers by order to make supplementary, incidental, consequential, transitory, transitional or saving provision as they consider necessary for the purposes, or in consequence, of the Act. Such provisions, by their nature, are considered appropriate for subordinate legislation. Section 52(2) provides that such an order may make different provision for different purposes and may modify any enactment, instrument or document. Section 53(3) provides that regulations under section 52 which add to, replace or omit any part of the text of an Act is to be made by way of affirmative resolution procedure. All other regulations under this provision can be made by way of negative resolution procedure because the conditions outlined in paragraph 7 for the use of affirmative procedure do not apply.

Relevant Provision: Section 56(2)

Power conferred on: The Scottish Ministers
Power exercisable by: Order made by Statutory Instrument
Parliamentary procedure: No parliamentary procedure

36. Section 56 of the Bill provides for the short title and commencement arrangements for the Bill.

37. Section 56(2) gives the Scottish Ministers power to appoint a day when provisions of the Bill shall come into force. Section 56(3) provides that different days can be appointed for different purposes.

38. It is standard procedure for such commencement provisions to be dealt with by subordinate legislation. Whilst the order, in common with the usual practice for such orders, is not subject to any parliamentary procedure as such, the Subordinate Legislation Committee will have the opportunity to consider the instrument in terms of its remit.