



## SCOTTISH EXECUTIVE

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Health Department  
Directorate of Service Policy and Planning

Health Planning and Quality Division  
St Andrew's House  
Regent Road  
Edinburgh EH1 3DG

### *Sent by Email*

Contact List: see attached

Telephone: 0131 244 2420

23rd September 2005

Dear Sir/Madam

### **CONSULTATION PAPER ON THE HUMAN TISSUE (SCOTLAND) BILL AND ISSUES RELATING TO ADULTS WITH INCAPACITY**

I am writing to invite comments on a range of issues related primarily to the donation of organs and tissue for transplantation by adults with incapacity. These are set out in detail in the Consultation Paper attached, which also deals with post-mortem and anatomical examinations.

The text of the Human Tissue (Scotland) Bill and its accompanying documents can be found on the website of the Scottish Parliament. The full text of the written evidence on the Bill submitted to the Health Committee can be found on the Committee's page in the Parliament's website. The Bill is already at Stage 1, with Stage 2 expected to start in mid-December and Stage 3 in early February 2006.

This timetable means that if we are to make changes to the Bill in response to this consultation, we need to ask for responses by **Monday 31 October** at the latest. I should like to assure you that this period, which is rather shorter than normal, in no way implies any undervaluing on the part of the Executive of the important and sensitive issues under consideration.

### **Consultation process**

We would be grateful if you would structure your comments by responding to the specific questions in the consultation document, as this will allow us to consider and analyse all responses in a comprehensive and prompt manner. Please feel free, however, to give us your views on any other issues raised by the consultation.

A web version of the Consultation Paper can also be accessed at [www.scotland.gov.uk/views/views.asp](http://www.scotland.gov.uk/views/views.asp) You can telephone Freephone 0800 77 1234 to find out where your nearest public internet access point is, if you prefer to submit your response by email. This should be sent to: [humantissueawiconsultation@scotland.gsi.gov.uk](mailto:humantissueawiconsultation@scotland.gsi.gov.uk)

## Submission of Responses

Responses to this consultation should be submitted by **Monday 31 October at the latest** to:

Ms Cheryl Paris  
Health Planning and Quality Division Branch 4  
Scottish Executive Health Department  
Ground Rear: East  
St Andrew's House  
EDINBURGH  
EH1 3DG

Fax No: 0131-244 2989

E-mail: [cheryl.paris@scotland.gsi.gov.uk](mailto:cheryl.paris@scotland.gsi.gov.uk)

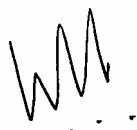
**If you have any queries, contact Cheryl Paris at 0131-244 2946.**

To help inform debate on the points covered by this consultation paper, the Scottish Executive intends to follow its normal practice of making copies of responses received available to the public in the Scottish Executive library at Saughton House, Broomhouse Drive, Edinburgh (tel 0131 244 4552) by 7<sup>th</sup> November. If respondents indicate that they wish all, or part, of their reply excluded from this arrangement, confidentiality will be strictly respected. All responses not marked confidential will be checked for any potentially defamatory material before being placed in the Scottish Executive library. To assist us in handling your response appropriately, it is important that you complete the attached 'Respondee Information Form' at Annex A.

An outline list of consultees is attached at Annex B. If there are other individuals or bodies who should be included, please either copy the Paper directly to them, preferably by email because of the time constraint, or ask the Departmental contact (as indicated above) to send them a copy.

I look forward to receiving your views on this consultation.

Yours faithfully



**W S SCOTT**

**RESPONDEE INFORMATION FORM**

Please complete the details below and attach it with your response. This will help ensure we handle your response appropriately:

Name:

Address:

Title of consultation:

1. Are you responding as:

- an individual   
on behalf of a group or organisation

2. Do you agree to your response being made public (in SE library and/or on SE website)?

- Yes   
No

Where confidentiality is not requested, we will publish your full response including your name (and address, where provided).

*If you do not wish these personal details to be published, please tick this box:*

Are you content for the Scottish Executive Health Department to contact you again in the future for consultation purposes?

- Yes   
No

## **The Scottish Executive Consultation Process**

Consultation is an essential and important aspect of Scottish Executive working methods. Given the wide-ranging areas of work of the Scottish Executive, there are many varied types of consultation. However, in general, Scottish Executive consultation exercises aim to provide opportunities for all those who wish to express their opinions on a proposed area of work to do so in ways which will inform and enhance that work.

While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body. Consultation exercises may involve seeking views in a number of different ways, such as public meetings, focus groups or questionnaire exercises.

Typically, Scottish Executive consultations involve a written paper inviting answers to specific questions or more general views about the material presented. Written papers are distributed to organisations and individuals with an interest in the area of consultation, and they are also placed on the Scottish Executive web site enabling a wider audience to access the paper and submit their responses<sup>1</sup>. Copies of all the responses received to consultation exercises (except those where the individual or organisation requested confidentiality) are placed in the Scottish Executive library at Saughton House, Edinburgh (K Spur, Saughton House, Broomhouse Drive, Edinburgh, EH11 3XD, telephone 0131 244 4552).

The views and suggestions detailed in consultation responses are analysed and used as part of the decision making process. Depending on the nature of the consultation exercise the responses received may:

- indicate the need for policy development or review
- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

If you have any comment about how this consultation exercise has been conducted, please send them to:

Ms Cheryl Paris  
Health Planning and Quality Division Branch 4  
Scottish Executive Health Department  
Ground Rear: East  
St Andrew's House  
Regent Road  
EDINBURGH  
EH1 3DG  
E-mail: [cheryl.paris@scotland.gsi.gov.uk](mailto:cheryl.paris@scotland.gsi.gov.uk)

<sup>1</sup> [www.scotland.gov.uk](http://www.scotland.gov.uk)

**LIST OF CONSULTEES**

- Action on Churches Together
- Age Concern Scotland
- Alzheimer's Scotland
- British Medical Association Scotland
- Capability Scotland
- Carers Scotland
- Chest, Heart & Stroke Scotland
- Enable
- Headway Scotland
- Law Society of Scotland
- Medical & Dental Defence Union Scotland
- Mental Welfare Commission
- Neurological Alliance Scotland
- Pamis
- Parkinson's Disease Society of the United Kingdom
- Professor Sheila McLean, University of Glasgow
- Royal College of Nursing
- Royal College of Pathologists Scottish Regional Council
- Royal College of Psychiatrists
- Scottish Coalition on Learning Disability
- Scottish Council on Human Bioethics
- Scottish Partnership for Palliative Care
- Scottish Law Commission
- Scottish Transplant Group
- Scottish Transplant Co-ordinators' Network
- Sheriffs' Association

## **HUMAN TISSUE (SCOTLAND) BILL: CONSULTATION ON ADULTS WITH INCAPACITY AND DONATION**

1. The Human Tissue (Scotland) Bill was introduced in the Scottish Parliament on 3 June 2005. References in this paper to the relevant provisions of the Bill are therefore to the provisions of the Bill as introduced. The Bill may be subject to amendment during its passage through the Scottish Parliament. It is with a view to any amendments relating to adults with incapacity that consultees' views are being sought.

2. The issues raised by the consideration of the position of adults with incapacity in the context of organ and tissue donation for transplantation fall into two broad categories: donation from deceased adults with incapacity and donation from living adults with incapacity. This paper considers each of these in turn.

### **Adults with Incapacity: Deceased Donors**

3. Section 6 of the Human Tissue (Scotland) Bill provides that adults – those aged 16 or over – may authorise the removal and use of a part of their body after death for one or more of the purposes set out in section 3(1): primarily transplantation, but also research, education or training and audit. No particular form is prescribed in the Bill for such authorisation, but carrying an organ donor card or putting one's name on the NHS Organ Donor Register will be regarded as forms of self-authorisation. Section 8 means that all existing written requests by adults will count as self-authorisations once the Bill comes into force. Section 6 also provides that authorisation may be withdrawn in signed writing. It is open to an adult to withdraw authorisation at any time.

4. If the adult dies without having left authorisation, section 7 comes into play, to enable the nearest relative (defined by the hierarchy in section 45) to authorise the removal and use of a part of the body of the adult for transplantation and also, unless the adult was known to have been unwilling, for one or more of the other purposes in section 3(1).

### **Authorisation during the lifetime of the adult with incapacity**

5. Under Scots law, adults are presumed to have legal capacity, although that presumption may be rebutted. A specific statutory framework in relation to adults with incapacity was introduced in Scotland by the Adults with Incapacity (Scotland) Act 2000.

6. The Bill does not make any specific provision as regards adults with incapacity authorising the use of their organs after their death. This means that the existing law will apply as regards legal capacity for giving authorisation during the lifetime of the adult.

7. Those adults who had authorised the removal and use of body parts prior to losing capacity would, after death, be treated in the same way as any other adult, so that the process set out in paragraphs 3 and 4 above would apply. The essential point is that the person must have had capacity at the time of giving authorisation in order for that authorisation to be of legal effect, ie at the point at which they decided to carry an organ donor card or put their name on the NHS Organ Donor Register. Similarly, an adult would require to have legal capacity in order subsequently to withdraw an existing authorisation.

**Question 1:**

**Is there any reason why the authorisation arrangements proposed for adults in general by the Bill should not apply to adults with incapacity, provided they had the capacity to make that decision at the time they started to carry an organ donor card or put their name on the NHS Organ Donor Register?**

**Question 2:**

**Does the fact that the adult may subsequently lose capacity, and therefore the capacity to withdraw an existing authorisation, raise any separate issues?**

8. There appears to be some uncertainty at present, though, as to whether a welfare attorney or guardian could, by virtue of their powers under the Adults with Incapacity (Scotland) Act 2000, give authorisation under the Bill on behalf of the adult with incapacity while the adult is still alive and the proxy powers are still active, as to what should happen after the adult's death. This would in practical terms mean the welfare attorney or guardian signing an organ donor card on behalf of the adult with incapacity, or putting the name of the adult with incapacity on the NHS Organ Donor Register. This issue was not addressed by the Scottish Law Commission, which considered only donations from living adults with incapacity.

9. Welfare attorneys and guardians must exercise their powers in accordance with the principles set out in section 1 of the 2000 Act. In terms of section 1(4), they would require to take into account the present and past wishes and feelings of the adult, so far as they can be ascertained by any means. This could, in theory at least, enable an attorney to give authorisation on behalf of an adult who, when capable, had expressed wishes in favour of donation but not given tangible expression to them prior to losing capacity. The Adults with Incapacity (Scotland) Act 2000 aimed at putting adults with incapacity as far as possible in the same position as capable adults for all important decisions, though there may be limits to how far a person with incapacity can be credited with altruism without the risk of exploitation or abuse. The Bill therefore provides an opportunity to put beyond doubt the issue of a welfare attorney or guardian's powers in relation to donation of body parts for transplantation after death, either by including a provision in the Bill itself or using the Bill to amend the Adults with Incapacity (Scotland) Act 2000.

**Question 3:**

**Should the Bill be used to put beyond doubt in future the issue of a welfare attorney or guardian's powers to give authorisation for the donation of body parts after the adult's death, where the adult with incapacity was known to have expressed a view as regards donation before losing capacity? If this should be possible, what proof, if any, should the welfare attorney or guardian be expected to provide of the donation wishes of the adult with incapacity?**

Authorisation after the death of the adult with incapacity

10. The powers of welfare attorneys and guardians under the 2000 Act cease on the death of the adult with incapacity. They therefore have no role to play once the adult is declared dead. There are, however, 2 issues in respect of adults with incapacity as regards authorisation by their nearest relative.

11. If someone had lacked capacity for many years prior to their death, it could be argued that the passage of time might invalidate any knowledge the nearest relative might have of the wishes of the adult. This situation could, of course, arise in relation to any adult, where the only conversation as to the use of body parts after death might have taken place 20 or

more years before death occurred. It might be argued that the significant difference with adults with incapacity is that they would not have been able to change their minds, either by making their revised views known to their nearest relative, or by themselves withdrawing their existing written authorisation, as is open to an adult to do at any time under section 6(2)(b) of the Bill.

**Question 4:**

**Does the fact that an adult who has lacked capacity for many years prior to death unduly prejudice the incapable adult, contrary to the spirit of the 2000 Act, when compared to any capable adult, as regards the opportunity to change their mind about donation?**

**Should the length of time an adult has lacked capacity render invalid any wishes in favour of donation which they had expressed while they still had capacity? If so, what would the appropriate length of time be?**

12. The other issue concerns an adult who dies having never had capacity, the implication being that they would never have been able during their lifetime to express any views about donation of body parts after death. Section 7(4) of the Bill provides that the nearest relative cannot give authorisation if they have ‘actual knowledge’ that the adult was unwilling for this to happen. If an incapable adult could not express unwillingness, section 7 would automatically allow the nearest relative to authorise donation of body parts from an incapable adult after death, since the definition of ‘adult’ within the Bill only requires that the person was 16 or over. There is no requirement for the adult to have had capacity to express any views on donation.

13. This may be compared with the approach under the Bill in relation to children. If a child who was 12 years or over dies without having themselves given authorisation under section 9, then section 10 enables a person who had parental rights in respect of the child to authorise removal and use of a part of the body of the child for one or more of the purposes set out in section 3(1). That authorisation cannot be given, however, if the person has ‘actual knowledge’ that the child was unwilling for this to happen. The Bill therefore accords to children aged 12 or over when they died the same respect for any views against donation which were expressed during their lifetime.

14. By contrast, section 11 of the Bill provides that a person who had parental rights in respect of a child who died *under* 12 years of age may authorise the removal and use of a part of the body of the child for one or more of the purposes in section 3(1) without requiring there to have been any reference to the views of the child during that child's lifetime. It might be considered therefore that the practical effect of long-term incapacity of an adult is to place an adult with incapacity under the Bill in the same situation as a child who died under 12 years of age, in that their views (by virtue of having been unable to express them due to the adult's incapacity) will not have been taken into account by their nearest relative in making the decision after the adult's death.

**Question 5:**

**Is there any problem with the role of the nearest relative of an adult with incapacity in respect of the fact that the nearest relative could in theory authorise the donation of body parts from a person who was an adult when they died but had never had capacity in life to express any wishes on the subject themselves?**

**Adults with Incapacity: Living Donors**

15. The issues of organ donation by adults with incapacity while alive was considered in the Scottish Law Commission report<sup>1</sup> which proposed the Adults with Incapacity legislation. The relevant passage is as follows:

**Organ donation**

5.60 Transplantation of a non-regenerative organ (a kidney for example) from a living incapable adult is not treatment to safeguard and promote the health of that adult. Accordingly, it would not fall under the general statutory authority of doctors to provide medical treatment that we have recommended in Recommendation 58 above. As we pointed out in our discussion paper the legality of transplants where the donor is incapable of consenting is not clear. The power of a tutor-dative to consent on behalf of the incapable adult may well be limited to procedures that carry only a minimal risk to the donor such as a skin graft or a blood donation. Suggestions have been made in recent English cases that organ donation from living incapable individuals should require the prior authority of the Court.

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<sup>1</sup> Report on Incapable Adults, Scottish Law Commission (Scot Law Com No. 151) – 14 July 1995

5.61 In our discussion paper we set out the arguments for and against allowing transplantation of non-regenerative tissue from a living adult mentally incapable of giving consent and asked for views as to whether such transplantation should be permitted and, if so, under what conditions. Transplantation to a close relative arguably confers an indirect benefit on the incapable donor. The donor may be distressed by the critical illness of the recipient and the death or serious illness of the recipient may deprive the donor of a carer. Transplantation can also be justified on public interest grounds in alleviating pain and suffering where this can be done without causing substantial harm to others. On the other hand, a mentally disabled person's health and wellbeing is no less worthy of consideration than that of any other person. The temptation to regard incapable people merely as a source of spare parts must be firmly resisted.

5.62 A sizeable minority of those responding to our request for views thought that such transplants should be prohibited altogether. The majority view was that the procedure should be allowable in exceptional cases. Among the conditions suggested were prior approval by the court, the unavailability of a suitable organ from any other source, the unavailability of any alternative suitable treatment, and that the death or continued serious ill-health of the recipient would severely diminish the quality of the donor's life. We have had further discussions with those involved with transplants in practice. We understand that recent advances in surgery and drug therapy to prevent rejection enable successful transplants to be achieved with organs from dead bodies and that transplants from living donors now form only a small proportion of all those undertaken. The British Medical Association's view is that it is not appropriate for "live, non-autonomous individuals to donate non-regenerative tissue or organs. This prohibition does not seem to result in patients being left untreated. Finally, as far as kidney donation is concerned, transplantation cannot be regarded as involving a minimal or low risk to the donor. We have come to the view that no changes are required in this area.

16. Since that report was published in 1995, attitudes to living donation have changed considerably, and the Scottish Transplant Group's *Organ Donation Strategy for Scotland* (June 2002) emphasises the scope for increasing living donor transplant activity further. At present, it is possible to transplant a kidney from a living donor, a living donor liver programme begins in Scotland on 1 April 2006 involving the transplantation of part of the liver, and transplantation of parts of lungs is also possible in other parts of the world. Various types of tissue can be transplanted from living donors, including regenerative tissue such as bone marrow.

17. The general approach to living donation of organs and tissue is set out in section 15 of the Bill (blood donation is not covered by the Bill). The Explanatory Notes for section 15 are as follows:

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.

Subsection (1) is intended to ensure that no organ or part of an organ can be removed from a living adult or child under any circumstances. ('Adult' means a person 16 years of age or over and

'child' means a person under the age of 16 – section 54(1).) That also applies to the removal from a living child of any tissue other than tissue which is regenerative, by which is meant tissue which, after injury or removal, is replaced by the body of a living person by natural processes (subsection (7)). This exception is to allow in particular bone marrow to continue to be transplanted between children, although subject to the overall system of scrutiny. Subject to subsections (3) and (5), an offence is committed if a person does any of these things and at the time knows, or might reasonably be expected to know, that the removal is from a living adult or child.

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

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

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

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

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

18. Although section 15 provides that the Scottish Ministers must be satisfied that no reward has been given and that certain conditions may apply in relation to live transplants, the policy intention is that Scottish cases will be scrutinised by the Human Tissue Authority. This would be achieved by means of section 49 of the Bill, which enables the Scottish Ministers to make arrangements with a public authority in the UK for that authority to assist them in relation to any functions under section 15(3).

19. The Bill is currently silent on the issue of organ and tissue donation by living adults with incapacity. At the moment, therefore, the provisions of the Adults with Incapacity

(Scotland) Act 2000 would apply. The 2000 Act does not specifically deal with organ or tissue donation by an adult with incapacity, but within Part 5 of the 2000 Act (Medical Treatment and Research), section 47 only allows a medical treatment or procedure that will safeguard or promote the physical or mental health of the adult.

20. Apart from the removal of regenerative tissue, such as bone marrow, for use in the adult's own treatment ('autologous use'), the Executive takes the view that organ or tissue donation from an incapable adult is unlikely ever to meet the section 47 AWI test of safeguarding or promoting that adult's *physical* health. Organ and tissue donation involve considerable risks and discomfort to the donor, and where the donation is to another person, are unlikely to bring about any direct improvement in the donor's state of physical well-being.

21. It is more difficult to determine whether being a live donor would benefit an adult who lacked capacity in terms of their *mental* health. Would they know they had been a donor? Would they derive any comfort or satisfaction from having given a new lease of life to someone they cared about? A North American legal case in 1996 ('Re Y') allowed a woman with incapacity to donate bone marrow to her sister, on the basis that doing so would allow her mother to care for her (the donor) more, and therefore was in the donor's 'emotional, social and psychological interests'. This type of argument could potentially apply in Scotland, in terms of meeting the section 47 AWI test of safeguarding or promoting the mental health of the adult. The test in Re Y, however, was what was in the donor's 'best interests'. The law in Scotland is however expressed in terms of 'benefit' to the donor, which may be interpreted as being narrower and more focused on the needs of the donor.

22. The Executive therefore believes that organ or tissue donation by an adult with incapacity for use by someone else does not fall clearly within the terms for authorisation of 'medical treatment' under Part 5 of the 2000 Act.

23. The only other avenue under the 2000 Act for authorising donation would be if a welfare attorney or guardian could use their powers under the Act. In that event, any intervention in the affairs of the adult would still be subject to the general principle under the Act that the intervention would require to 'benefit' the adult. Again, therefore, although the position has not been tested in the courts, the Executive takes the view that it is not clear that

that the powers of a welfare attorney or guardian could be used under the remaining Parts of the 2000 Act to authorise any intervention involving the adult as an organ or tissue donor.

24. The Executive is aware of arguments that adults with incapacity should not be denied the opportunities for altruism which are available to other adults. It is also aware that the Department of Health published on 11 July draft Regulations – the Human Tissue Act 2004 (Transplants) Regulations 2005 – which would allow, in the rest of the UK, the removal of organs or parts of organs from an adult with incapacity, provided the matter had been referred to the Human Tissue Authority, and that each case is decided by a panel of no fewer than 3 members of the Authority. More detail is included in paragraphs 35-38 of the draft Code of Practice on Consent issued by the Human Tissue Authority on 11 July. Unless the position is modified as a result of the DH/HTA consultation process, it will be possible in the rest of the UK to take a case-by-case approach to the donation of organs, parts of organs or non-regenerative tissue by an adult with incapacity. The Department of Health and the Human Tissue Authority are also checking that the position is consistent with the terms of the Mental Capacity Act 2005, which applies to England and Wales.

25. The Executive believes that it should be possible for adults with incapacity to donate regenerative tissue, subject to independent scrutiny of each case, but that organs, parts of organs and non-regenerative tissue should not be allowed to be removed from a living adult with incapacity for the purposes of transplantation to another person. The Executive wishes to put the position in Scotland beyond doubt by using the Human Tissue (Scotland) Bill.

**Question 6:**

**Are consultees generally in favour of the prohibition of the removal of organs, parts of organs and non-regenerative tissue from a living adult with incapacity for the purpose of transplantation to another person? If not, should consideration be given to making the position in Scotland consistent with that proposed for the rest of the UK, ie a mechanism should be put in place to allow the Human Tissue Authority to consider the donation of organs, parts of organs or non-regenerative tissue by a living adult with incapacity?**

26. Similar issues arise in relation to regenerative tissue, such as bone marrow. Although there are risks and discomfort associated with the donation of bone marrow, the Re Y case indicates that circumstances could arise in which it could be argued that there would be a mental health benefit to the adult with incapacity from the donation of regenerative tissue to another person. It is also the case that a broad view can be taken of ‘benefit’ as encompassing an overcoming of the limitations created by incapacity, so as to permit something which the adult could reasonably be expected to have chosen to do if capable, even though the action is of a gratuitous or unselfish nature. Some of those who have provided written evidence to the Health Committee about the Bill have therefore suggested that it should be possible, with proper safeguards, for adults with incapacity to donate *regenerative* tissue. This would be consistent with the position in the rest of the UK, and with the policy on living children which the Executive has embodied in the Bill.

27. Because of the range of circumstances which can arise, the Executive takes the view that it would be unwise to exclude absolutely adults with incapacity from donation of regenerative tissue. Such donation should be possible, however, only with stringent safeguards. Each case would have to be looked at independently on its own merits. The Executive wishes to make the position in Scotland clear beyond doubt by using the Human Tissue (Scotland) Bill.

**Question 7:**

**Do you agree that it should be possible for adults with incapacity to donate regenerative tissue, subject to independent scrutiny of each case?**

28. There is a general assumption that if such donation were to be permitted, it would be to another close member of the adult with incapacity’s family. The scrutiny of living donation, however, has traditionally covered cases where the potential donor and recipient are unrelated, and it is only now being extended to cases where they are related. The Human Tissue Authority consultation on its draft Code on Consent suggests (paragraph 38) that an example of donation would be where the incapacitated adult may be the only suitable donor of tissue for a sibling or close family member, but that is simply an example. It is not suggested that donation to unrelated people would be impossible. The draft Code on

Donation of organs, tissues and cells for transplantation makes it clear that the Human Tissue Authority will in future consider non-directed (also known as ‘altruistic’) donation, which is when a person offers to donate to a complete stranger. If the approach to adults with incapacity is one of offering them the same range of opportunities as are available to other adults, should donation of regenerative tissue by an adult with incapacity be restricted to those with whom the adult has a close family relationship?

**Question 8:**

**Should adults with incapacity be able to donate regenerative tissue only to close family members, or should non-directed donation also be open to them?**

29. The question then arises: who can authorise such donation on the part of the adult with incapacity? The Executive takes the view that unless the regenerative tissue is to be used as part of the adult’s own treatment, the Adults with Incapacity (Scotland) Act 2000 does not give the welfare attorney or guardian the power to authorise its removal for transplantation into another person. The Executive has identified 2 options for the creation of a system of authorisation. The first is to confer an appropriate function on the Scottish Ministers, so that they could ask the Human Tissue Authority to scrutinise each case, including the protection that decisions must be taken by a panel of at least 3 members of the Authority (see paragraph 18). This would have the advantage of consistency with the handling of these cases in the rest of the UK. The Regulations to be made under section 15(3) must include provision as to appeals against decisions of the Human Tissue Authority.

30. The other option is to adapt the safeguards contained in section 51 of the 2000 Act in respect of research. Under section 51, no research can be carried out on an adult with incapacity unless research of a similar nature cannot be carried out on an adult with capacity. The equivalent would be to include a protection that regenerative tissue could not be removed from an adult with incapacity unless there was no other suitable practicably available donor with capacity. Section 51 also provides that consent can be obtained from any guardian or welfare attorney who has the power to consent, or, where there is no welfare attorney or guardian, from the adult’s nearest relative. The Bill could make clear that the powers of a welfare attorney or guardian, whom failing the nearest relative (as defined in section 45),

could cover the authorisation of the removal of regenerative tissue for purposes of transplantation to another person. Section 52 of the 2000 Act provides for a right of appeal to the sheriff and then, with the leave of the sheriff, to the Court of Session, and this could be adapted to cover the removal of regenerative tissue for transplantation to another person.

**Question 9:**

**If the donation of regenerative tissue from an adult with incapacity is to be possible, should the case by case scrutiny be provided:**

**(a) by conferring a function on the Scottish Ministers so that they can refer cases to the Human Tissue Authority, as will happen in the rest of the UK;**

**or**

**(b) by adapting the protections in relation to research which are already incorporated in the Adults with Incapacity (Scotland) Act 2000, including an appeal provision?**

**In the latter case, should there be a provision that such tissue could not be removed unless there was no donor with capacity who was a suitable match?**

**Post-Mortem Examinations and Anatomical Examinations under the Anatomy Act 1984**

31. While the discussion in respect of adults with incapacity has centred on donation for transplantation of organs and tissue by living adults with incapacity, the principles of authorisation and respecting after death the wishes people expressed while alive also underpin Parts 2 and 3 of the Bill. Part 2 makes provision in respect of hospital post-mortem examinations and the retention and use of tissue samples and organs from such an examination for a similar system of authorisation first of all by an adult in life, then by a nominee or the nearest relative. Part 3 creates a similar system of authorisation in respect of tissue samples and organs retained from a post-mortem examination instructed by the Procurator Fiscal, once those samples and organs are no longer required for the Fiscal's purposes. Part 5 amends the Anatomy Act 1984, under which people can donate their bodies for anatomical examination for the purposes of teaching, studying or research.

32. The same issues regarding adults with incapacity arise as they do in the context of the donation of organs or tissue after death for the purposes set out in section 3(1) of the Bill.

The Executive considers that in the interests of consistency it should adopt the same approach as for transplantation, ie that adults who prior to losing capacity had authorised these uses of their body or body parts after death should be treated in the same way as any other adult. The Bill should therefore be used as necessary to clarify the position.

**Question 10:**

**Is there any reason why the authorisation arrangements proposed for adults in general in relation to decisions relating to post-mortem examinations or the Anatomy Act 1984 should not apply to adults with incapacity?**

33. If there are any other issues which have not been raised in this Consultation Paper but which you would like the Executive to take into account, please include these in your response.