

# **Scottish Council on Human Bioethics**

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**Date: 24 August 2005 – The Scottish Parliament – Health Committee**

## **Human Tissue (Scotland) Bill**

### **Consultation response on behalf of the Scottish Council on Human Bioethics:**

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity composed of doctors, lawyers, psychologists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribe are set out in the **United Nations Universal Declaration of Human Rights** which was adopted and proclaimed by the UN General Assembly by resolution 217A (III) on 10 December 1948.

The SCHB is very grateful to the **Health Committee** of the **Scottish Parliament** for this opportunity to respond to the consultation on the **Human Tissue (Scotland) Bill**. It welcomes the Committee's intent to promote public consultation, understanding and discussion on this topic.

In addressing the consultation, the SCHB has formulated the following responses<sup>1</sup>:

#### **TRANSPLANTATION ETC.**

##### **Scope of the proposed Bill**

1. The scope of the proposed Human Tissue (Scotland) Bill is unclear but should not include human embryos, fetuses or reproductive cells under "body parts". In the Human Tissue Act 2004 which extends to England, Wales and Northern Ireland, live gametes and embryos are excluded as they are already regulated under the Human Fertilisation & Embryology Act 1990.

##### **Deceased Person's wishes should be respected**

2. The SCHB very much welcomes the provisions in the draft Bill which support the principle that the deceased person's wishes should be respected as long as they reflect an "informed decision", whether these have been expressed verbally or in writing (for example, using donor cards or a registration on the NHS Organ Donor Register)<sup>2</sup>. This principle implies that when the deceased's wishes are clear the nearest relatives should not have a right of veto.
3. However, the SCHB is concerned that persons are sometimes not adequately informed of what is involved when they consider donating their bodies or their parts after death for purposes such as medical research and education or training. For example, the SCHB is aware that many individuals do not realise that this may include the dissection of a naked body in front of large number of undergraduate medical students. Thus the Council would like to see better information being available to the Scottish general public in order to enable the important principle of 'informed consent' to exist.

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<sup>1</sup> Because of the number of concerns expressed by the SCHB with respect to this Bill, the number of pages was not limited to four A4 sides.

<sup>2</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

**No removal of body parts should take place when the wishes of the deceased person are unknown**

4. The SCHB is extremely concerned about the potential for mistakes resulting from Section 7 of the proposed bill if a 'nearest relative' is able to authorise the removal of body parts from a deceased person who has not left any specific expression of wishes<sup>3</sup>. This is because there is no certainty that the decisions of a 'nearest relative' is a true reflection of the wishes of the person at the time of his or her death.
5. Unfortunately, the proposed bill seems to have been drafted with the aim of increasing the supply of organs for transplantation, or of human material for education, training, research or audit at the expense of one of the most important ethical principles in medicine, namely the principle of 'informed consent'. Indeed, to go beyond the express and specific wishes of a person by letting others make important decisions on what they 'assume' or 'presume' are the wishes of this person is what specifically lead to the scandal at Alder Hey Children's Hospital in Liverpool. At this hospital, body parts of children were retained after post-mortem examination when healthcare professionals 'presumed' that this would be acceptable to parents without consultation.
6. In the Policy Memorandum of the Human Tissue (Scotland) Bill, it is indicated in paragraph 22 that:

*"the public's reaction to the revelations about organ retention at post-mortem examination shows that, for many people, presumed consent does not represent a valid form of consent. They feel it deprives them of a sense of control over what happens to their bodies, or the bodies of their loved ones, after death."*<sup>4</sup>

Accordingly, it is the opinion of the SCHB that the draft Human Tissue (Scotland) Bill may enable the same unacceptable mistakes to be made as in Alder Hey Children's Hospital which would undermine public confidence in the organ transplantation system.

In addition to the above, the following arguments can be made against the removal of body parts when the wishes of the deceased person are unknown.

***The removal of body parts when the wishes of the deceased person are unknown may be an unethical intervention***

7. Any decision that may go against the real wishes of the deceased person would enable a very unethical situation to exist. It would only be acceptable if the nearest relative was absolutely certain that the deceased person was aware of the authorisation system, had not objected to the procedure and had very recently shared his or her wishes with his or her nearest relative. Even if the proposed bill resulted in only one decision being made by a nearest relative which did not reflect the real wishes of a deceased person, then the bill could be considered as enabling unethical practices to exist.
8. The SCHB also agrees that it would be extremely difficult for absolutely everyone in Scotland to be aware of the system in place. Promises that advertising and publicity campaigns will be undertaken to promote the message that people should not simply carry a donor card or put their name on the Register, but also let their nearest relatives know of their wishes<sup>5</sup>, will never be sufficient. Talking about death can still be considered taboo in many sections of Scottish society and members of the general public are entitled to not have to address this topic.

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<sup>3</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

<sup>4</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 22., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

<sup>5</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 13., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

As with the present voting procedure at elections, people are entitled and have the right, in Scotland, not to make a specific decision. Thus, it would be unacceptable for electoral officers, after an election, to ask the nearest relatives of those who did not vote (either directly or using a proxy) to 'presume' the wishes of those who did not vote and thereby cast a vote for them.

9. Accordingly, the SCHB believes that for the draft bill to support ethical practice and public confidence it is imperative to exclude the possibility for nearest relatives to authorise the removal of body parts from a deceased person when his or her wishes are not known. In other words, Section 7 of the proposed Bill should be substantially amended.
10. The only instances where authorisation from a nearest relative may be considered are when the person who has died is a child or a person who did not have the capacity to consent to such a procedure while still alive. This would then reflect the provisions in the European Convention on Human Rights and Biomedicine whereby Article 6 (Protection of persons not able to consent) states that:

*"2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.*

*The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.*

*3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure."*

#### **Nearest relatives may not know the wishes of the deceased person**

11. The manner in which a nearest relative makes a decision concerning a relative who has died without leaving any prior wishes may be extremely problematic.

For example, Section 7(4)(a) of the draft bill indicates that:

*"The nearest relative may not give authorisation ... if the relative 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"*

But the expression 'actual knowledge' is undefined, extremely unclear and is open to abuse. For example, relatives may only have discussed transplantation with the deceased person a number of years before the death took place and may not, in any way, represent a true reflection of the wishes of the person at the time of his or her death.

12. In addition, a problem arises if a person does not trust his or her relatives concerning the decision to use his or her body parts after death. Indeed this person cannot stop his or her potentially unknown or unreliable relatives making the decision to use his or her body parts after death in the present UK context which does not have a national register opposing organ donation.
13. Furthermore, even the Policy Memorandum of the draft bill accepts that nearest relatives are 'changing their mind' with respect to what they believe are the wishes of the deceased person when these have not been communicated. Indeed, in paragraph 10 it states that:

*"For reasons which are not entirely clear, but which may be related to the effect of issues surrounding retention of organs at post-mortem examination, in ... Scotland, the relatives' refusal rate where the deceased's wishes are not known has risen from just over 30% in the early 1990s to around 49% now<sup>6</sup>."*

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<sup>6</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

14. Finally, in the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin<sup>7</sup> it is indicated that:

*“It is the expressed views of the potential donor which are paramount in deciding whether organs or tissue may be retrieved.”*

15. Thus, in the context of what is believed, by many, to be a gradual disintegration of family and social structures in Scotland it is very questionable whether the nearest relatives mentioned in Section 45 of the draft bill are aware of the wishes of the deceased person or even knew him or her when he or she was still alive.

***The procedure may be challenged at the European Court of Human Rights***

16. The SCHB was surprised to note in paragraph 28 of the Policy Memorandum that<sup>8</sup>:

*“The Executive is satisfied that the provisions of the Bill are compatible with the European Convention on Human Rights.”*

17. Indeed, it is the opinion of the SCHB that Section 7 of the draft Human Tissue (Scotland) Bill relating to the power of relatives to authorise the use of body parts of a deceased person who has not left any wishes may be open to a legal challenge at the European Court of Human Rights under the European Convention of Human Rights and specifically under:

- Article 8 (Right to respect for private and family life)
- Article 9 (Freedom of thought, conscience and religion)
- Article 10 (Freedom of expression)

18. This is all the more a possibility since the European Convention on Human Rights and Biomedicine can be used by the European Court to seek guidance<sup>9</sup> and this instrument indicates in Article 5 (General rule)<sup>10</sup> that:

*“- An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.*

*This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.”*

19. Thus, if a deceased person was not aware of (1) the system of consent/authorisation in place and (2) the possible destiny of his or her body or its parts (transplantation, research, etc.), and the use of the body or its parts did go ahead without the individual having given his informed consent, there may be grounds for taking the case to the European Court of Human Rights. This is because the European Convention on Human Rights and Biomedicine requires informed consent to take place before any intervention is envisaged. And in this case an intervention would also include a procedure after death under the spirit of the law.

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<sup>7</sup> Explanatory Report: Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin paragraph 102. <http://conventions.coe.int/Treaty/en/Reports/Html/186.htm>

<sup>8</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 28., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

<sup>9</sup> Even if the UK has not ratified this instrument the Court can still use the provisions found in this Biomedical Convention as guidance on ethical matters.

<sup>10</sup> Convention on Human Rights and Biomedicine, <http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc>

### **Surplus or residual tissue**

20. In paragraph 24 of the Policy Memorandum it is indicated that:

*“Bone and other tissue are usually regarded as waste products, in that they would normally be discarded from an operation or a diagnostic investigation such as a biopsy. Provisions relating to surplus or residual tissue appear in the Human Tissue Act 2004. The Executive’s policy, however, is that the arrangements for the authorisation of the use of surplus tissue can be dealt with satisfactorily by guidance and an appropriate authorisation form. It sees no need to introduce measures in this area more stringent than those which apply to the consent a living person gives to the carrying out of an operation.”*

21. In this respect, the SCHB concurs that any use of human waste products after surgery or any other procedure should be expressly authorised by the person from which they originated or his or her representative or an authority or a person or body provided for by law.

### **Extra-territorial Provisions**

22. In the same manner as Article 4 of the United Nations’ *Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography*<sup>11</sup>, the SCHB agrees that extra-territorial provisions should be included in the proposed Human Tissue (Scotland) Bill making it an offence for habitual residents in Scotland going abroad to undertake transplantation procedures which are prohibited in Scotland and considered as organ trafficking.

### **Observing international legislation**

23. In drafting new legislation relating to organ and tissue donation and transplantation, the SCHB is of the view that the Scottish Parliament should ensure that it complies (especially with respect to minors and persons with mental disability) to the following Council of Europe legislation:

**A. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin**<sup>12</sup>.

**B. Convention on Human Rights and Biomedicine**<sup>13</sup>,

And in Chapter VI (Organ and tissue removal from living donors for transplantation purposes) of this European Convention it is stated that:

#### **Article 19 – General rule**

- 1 *Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.*
- 2 *The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.*

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<sup>11</sup> Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography, <http://www.unhcr.ch/html/menu2/dopchild.htm>

<sup>12</sup> Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, <http://conventions.coe.int/Treaty/en/Treaties/Word/186.doc> - Adopted on 24 January 2002 but has not yet entered into force - Legally binding if ratified by a country - The United Kingdom has not signed nor ratified this additional Protocol

<sup>13</sup> Convention on Human Rights and Biomedicine, <http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc> - Entered into force on 1 December 1999 - Legally binding if ratified by a country - The United Kingdom has not signed nor ratified this Convention

## **Article 20 – Protection of persons not able to consent to organ removal**

- 1 *No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.*
- 2 *Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:*
  - i *there is no compatible donor available who has the capacity to consent;*
  - ii *the recipient is a brother or sister of the donor;*
  - iii *the donation must have the potential to be life-saving for the recipient;*
  - iv *the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body;*
  - v *the potential donor concerned does not object.*

24. Moreover, as with the Hague Convention on the International Protection of Adults<sup>14</sup>, the SCHB would like to see the United Kingdom ratify, as soon as possible, the above Council of Europe legal instruments on behalf of Scotland.

## **HOSPITAL POST-MORTEM EXAMINATIONS**

### **Right to be provided with information**

25. In paragraph 41 of the Policy Memorandum it is indicated that for consent to be valid in law it is generally expected to follow the provision of information, but that many people, parents in particular, do not want to be given details about organ removal, retention and use<sup>15</sup>.
26. The SCHB agrees with this statement but the offer of information should always be given.

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<sup>14</sup> Convention on the International Protection of Adults, [http://www.hcch.net/index\\_en.php?act=conventions.text&cid=71](http://www.hcch.net/index_en.php?act=conventions.text&cid=71) - Legally binding if ratified by a country - Adopted on 13 January 2000 but has not yet entered into force - The United Kingdom has ratified the Convention on 5 November 2003 (but for Scotland only) - <http://www.scotland.gov.uk/health/mentalhealthlaw/millan/Report/rnhs-37.asp>

<sup>15</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 41., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>