

# Scottish Council on Human Bioethics

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Date: 9 June 2004 - Scottish Executive - Health Department

## Consultation Paper on the Legislation Relating to Organ and Tissue Donation and Transplantation

### General Remarks:

**Note 1:** In drafting new legislation relating to organ and tissue donation and transplantation, **the Scottish Council on Human Bioethics (SCHB)** is of the view that the Scottish government should ensure that it respects the following international legislation. In addition, it should ensure that the language and expressions used in these international texts are similar to those of any future Scottish legislation in order to avoid misunderstandings and confusion:

### United nations

#### **(1) Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the United Nations Convention against Transnational Organized Crime**

This Protocol was adopted on 15 November 2000 but has not yet entered into force<sup>1</sup>.

Indeed, in Article 3 (Use of terms) of this Protocol it is stated that:

*For the purposes of this Protocol:*

*(a) "Trafficking in persons" shall mean the recruitment, transportation, transfer, harbouring or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs;*

#### **(2) Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography**

This Protocol entered into force on 18 January 2002<sup>2</sup>

In Article 3 of this Protocol it is stated that:

*1. Each State Party shall ensure that, as a minimum, the following acts and activities are fully covered under its criminal or penal law, whether such offences are committed domestically or transnationally or on an individual or organized basis:*

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<sup>1</sup> Legally binding if ratified by a country - United Kingdom has signed but not ratified this Protocol.

<sup>2</sup> Legally binding if ratified by a country - United Kingdom has signed but not ratified this Protocol.

*(a) In the context of sale of children as defined in article 2:*

*(i) Offering, delivering or accepting, by whatever means, a child for the purpose of:*

***b. Transfer of organs of the child for profit;***

Moreover in Article 4 it is indicated that:

*1. Each State Party shall take such measures as may be necessary to establish its jurisdiction over the offences referred to in article 3, paragraph 1, when the offences are committed in its territory or on board a ship or aircraft registered in that State.*

*2. Each State Party may take such measures as may be necessary to establish its jurisdiction over the offences referred to in article 3, paragraph 1, in the following cases:*

*(a) When the alleged offender is a national of that State or a person who has his habitual residence in its territory;*

*(b) When the victim is a national of that State.*

*3. Each State Party shall also take such measures as may be necessary to establish its jurisdiction over the aforementioned offences when the alleged offender is present in its territory and it does not extradite him or her to another State Party on the ground that the offence has been committed by one of its nationals.*

*4. The present Protocol does not exclude any criminal jurisdiction exercised in accordance with internal law.*

The **Scottish Council on Human Bioethics** supports such extra-territorial provisions making it an offence for habitual residents in Scotland going abroad to undertake procedures which are prohibited in Scotland.

## **Council of Europe**

### **(3) Convention on Human Rights and Biomedicine**

Entered into force on 1 December 1999<sup>3</sup>.

In Chapter VI (Organ and tissue removal from living donors for transplantation purposes) 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>3</sup> Legally binding if ratified by a country - The United Kingdom has not signed and not 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.*

Moreover, in Chapter VII (Prohibition of financial gain and disposal of a part of the human body) it is indicated that:

**Article 21 – Prohibition of financial gain**

*The human body and its parts shall not, as such, give rise to financial gain.*

**Article 22 – Disposal of a removed part of the human body**

*When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.*

**(4) Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin**

Adopted on 24 January 2002 but has not yet entered into force<sup>4</sup>.

As with the **Hague Convention on the International Protection of Adults (with Incapacity)**<sup>5</sup>, the **Scottish Council on Human Bioethics** would like to see the United Kingdom ratify, as soon as possible, the above Council of Europe legal instruments on behalf of Scotland.

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<sup>4</sup> Legally binding if ratified by a country - The United Kingdom has not signed and not ratified this additional Protocol

<sup>5</sup> 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).

## European Union

(5) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

(6) Draft European Parliament Legislative Resolution on the Initiative of the Hellenic Republic with a view to adopting a Council Framework Decision concerning the prevention and control of trafficking in human organs and tissues (7247/2003 – C5-0166/2003 – 2003/0812(CNS))

### Note 2:

With respect to the possibility of removing organs from a deceased person, the Human Tissue Act 1961 in the UK states in Section 1 (Removal of parts of bodies for medical purposes) that:

*1. If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of his body after death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body of any part or, as the case may be, the specified part, for use in accordance with the request.*

*2. Without prejudice to the forgoing subsection, the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purposes if, having made such reasonable inquiry as may be practicable, he has no reason to believe -*

*a. that the deceased had expressed an objection to his body being so dealt with after his death, and has not withdrawn it; or*

*b. that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.*

Section 1(1) of the Act roughly equates to what is generally referred to as an ‘opting in’ system. In other words, it requires the individual to take a positive decision in favour of donating organs and tissue after death for purposes of transplantation.

Section 1(2) of the Act, on the other hand, can be described as being similar to an ‘opting out’ or ‘presumed consent’ system. In other words, it is based on the supposition that organs and tissue can be retrieved after death for transplantation provided the dead person had not registered a prior objection to this.

Generally, ‘opting out’ systems may exist with or without the consent of relatives or close personal contacts.

The **Scottish Council on Human Bioethics** has not taken a position on whether or not an ‘opting in’ or ‘opting out’ scheme would be preferable in possible future Scottish legislation. However, the SCHB considers it crucial that organs or tissue should only be removed from a deceased person if this person has given his or her prior informed consent to the procedure. In other words, if a system is put into place in which there is any uncertainty about the expressed wishes of the deceased person and body parts are removed, then the procedure can only be considered as completely unethical.

### Note 3:

The Scottish Council on Human Bioethics considers that:

- the use of the expression “cadaveric donor” in the consultation paper (paragraph 7) is inappropriate. To be able to be a “donor” a person must have the possibility to make a choice to give. This is not the case with a cadaver since dead persons are not able to make ‘choices’. Thus, it would be more appropriate to use the terms “removal

from deceased persons” as in the recent Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin.

- an organ donor card and/or the registration on the NHS Organ Donor Register cannot be regarded as an advance directive (as in paragraph 11 of the consultation document). Indeed, advance directives can only address interventions on living persons, not dead ones. It would thus be more appropriate to use an expression such as “transplantation will” or something similar.

- the use of the expression “autonomy of deceased individuals” in paragraph 15 of the consultation paper is inappropriate since dead persons cannot have any autonomy.

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

**Note: Not all questions will be addressed**

### **Part 1: Transplantation of organs and tissue from people who have died**

#### **Question 1:**

**In the light of the legislation being proposed for the rest of the UK, and in Scotland in respect of hospital post-mortem examinations, do you agree there should be new legislation in Scotland in respect of organ and tissue transplantation?**

#### **Scottish Council on Human Bioethics Response:**

Yes, the SCHB concurs that new legislation in Scotland should be prepared concerning organ and tissue transplantation in order to reflect developments in biomedical possibilities and better protect the persons concerned.

The SCHB agrees with the Scottish Transplant Group and the Review Group on Retention of Organs at Post-Mortem that having a single piece of legislation governing organ donation *and* hospital post-mortem examinations has been a source of confusion in the public mind.

#### **Question 2:**

**- Should the system of organ and tissue donation in Scotland rest on the concept of ‘authorisation’?**

#### **Scottish Council on Human Bioethics Response:**

Yes, the system of organ and tissue donation in Scotland should rest on the concept of authorisation.

The possibility for the next of kin to authorise the retrieval of organs when an individual has left no wishes (Consultation: paragraph 18 - Adults and Mature Children - indent 4) should not be possible in an ‘opting in’ i.e. informed consent system. If body parts are removed without any explicit prior informed consent of the deceased person, then the procedure would be unethical.

In the case of an ‘opting out’ system, the next-of-kin could be able to authorise the removal of body parts. But this would only be ethical if the next-of-kin is absolutely certain that the deceased person was aware of the ‘opting out’ system and had not objected to the procedure.

**- If someone has decided to carry an organ donor card or add their name to the NHS Organ Donation Register, is there any role for a nominated person?**

**Scottish Council on Human Bioethics Response:**

No, the SCHB is of the opinion that if someone has decided to carry an organ donor card or add his or her name to the NHS Organ Donation Register, then there is no role for a nominated person. There would otherwise be a potential for confusion where both an expression of wishes and a nominated person exist. Moreover, the drafting of regulations relating to nominated persons would create new ethical issues.

**Question 3:**

**In respect of *children*, what provision should the new legislation make for situations where the parents take a different view on whether organ retrieval should go ahead, or where the hospital has been dealing with only one of the parents?**

**Scottish Council on Human Bioethics Response:**

The SCHB is of the view that everything should be done so that both parents participate in the decision making process relating to whether or not organ retrieval should go ahead. If parents disagree on the course to take, then organ retrieval should not go ahead.

**Question 4:**

**In relation to *adults* and *mature children*, should the carrying of an organ donor card, or registering his or her name on the NHS Organ Donor Register be sufficient indication of the individual's wishes, or should some further proof be required? If so, what form should that further proof take? How should verbally expressed wishes be witnessed?**

**Scottish Council on Human Bioethics Response:**

The SCHB agrees that in relation to adults and mature children, the carrying of an organ donor card, or the registering of their names on the NHS Organ Donor Register should be sufficient indication of the individuals' wishes. Verbally expressed wishes should be witnessed by two persons who are assured that the person has the capacity to make such a decision.

**Question 5:**

**If there are no next-of-kin, should organ and tissue retrieval take place on the basis that the potential donor carried a donor card or had registered on the NHS Organ Donor Register? If there are no next-of-kin and no expression of wishes by the deceased, should there continue to be a role for the 'person lawfully in possession of the body', or in those circumstances should organ retrieval simply not proceed?**

**Scottish Council on Human Bioethics Response:**

The SCHB agrees that if there are no next-of-kin, organ and tissue retrieval should take place on the basis that the deceased person carried a donor card or had registered his or her decision on the NHS Organ Donor Register.

If there are no next-of-kin and no expression of wishes by the deceased, there should be no role for the 'person lawfully in possession of the body' to make a decision on organ retrieval since he or she cannot reflect the wished of the deceased person. Therefore, in these circumstances no organ retrieval should take place.

**Question 6:**

**Should the legislation attempt to balance the wishes of the deceased against those of the surviving relatives, where these are in opposition?**

**Scottish Council on Human Bioethics Response:**

The principle of respecting the past wishes of the deceased person should take priority over the wishes of surviving relatives. If the deceased person has left no wishes then no organ retrieval should take place.

**Question 7:**

**Should there be a separate Register for those who wish to record their objection to organ donation?**

**Scottish Council on Human Bioethics Response:**

There should not be a separate Register for those who wish to record their objection to organ donation unless the Scottish Government decides to set up an 'opting out' system and it is absolutely certain that each and every person in Scotland is aware of this system and the Register.

**Question 8:**

**Should the Scottish legislation include 'friend of longstanding' in the hierarchy of 'relatives'? If so, for how long should the friendship have lasted for these purposes?**

**Scottish Council on Human Bioethics Response:**

The SCHB agrees that future Scottish legislation should include a 'friend of long-standing' in the hierarchy of 'relatives' but it should also make sure that the relevant person is an extremely close friend with a friendship lasting over several years.

**Question 9:**

**Are there reasons for wanting to apply the penalties proposed in the hospital post-mortem examination context to cadaveric organ and tissue retrieval?**

**Scottish Council on Human Bioethics Response:**

If the new legislation does not propose to introduce a system of penalties in relation to the retrieval of organs and tissue from deceased persons for purposes of transplantation it will be contravening Article 26 (Sanctions) of the Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin which states that:

*Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Protocol.*

**Question 11:**

**Should the new legislation proposed for Scotland continue the provision of the 1961 Act requiring the doctor removing organs for transplantation to satisfy himself that life is extinct, or should there be specific provision that he should satisfy himself that the brain stem death tests have been performed adequately?**

**Should the provision be retained if it is decided that organs and/or tissue could be retrieved by someone acting under the direction of a registered medical practitioner? (see paragraphs 37-40)**

**Scottish Council on Human Bioethics Response:**

The SCHB is of the view that specific provisions should exist which enable the physician removing the organs for transplantation to be satisfied that brain stem death tests have been performed adequately.

**Question 12:**

**Should the new legislation in Scotland allow for the retrieval of organs under the supervision of a registered medical practitioner?**

**Scottish Council on Human Bioethics Response:**

Members of the SCHB concurred that only a registered medical practitioner should be able to remove organs or tissue. Otherwise, the removal may become a matter of convenience where, for instance,

- 1) it is up to the technician to perform the procedure;
- 2) the procedure is undertaken to provide "practice" for medical students;
- 3) the NHS does not provide a sufficient number of qualified staff to comply to the EU Working Times Directive.

**Question 13:**

**Should the new legislation in Scotland allowing for retrieval of tissue under the supervision of a registered medical practitioner?**

**Scottish Council on Human Bioethics Response:**

Members of the SCHB concurred that only a registered medical practitioner should be able to remove organs or tissue. Otherwise, the removal may become a matter of convenience where, for instance,

- 1) it is up to the technician to perform the procedure;
- 2) the procedure is undertaken to provide "practice" for medical students;
- 3) the NHS does not provide a sufficient number of qualified staff to comply to the EU Working Times Directive.

**Question 14:**

**Is there general support for the proposal that the new legislation should include a provision to put beyond doubt the legality of taking the minimum action necessary to preserve a body so that consultation on transplantation can take place?**

**Scottish Council on Human Bioethics Response:**

The SCHB supports the proposal that the new legislation should include a provision to put beyond doubt the legality of taking the minimum action necessary to preserve a human body so that consultation on transplantation can take place.

**Question 15:**

**Should new legislation in Scotland make provision for ‘required request’?**

**Scottish Council on Human Bioethics Response:**

Yes, the possibility of enabling ‘required requests’, in which staff in intensive care environments must *always* approach the family about organ donation when medical treatment has stopped and death has been confirmed by brain stem tests, should be taken into account in any new Scottish legislation.

It may then encourage more positive attitudes within the NHS by taking away the feeling that complying with a request for organ donation should be done as a favour to the transplant unit.

**Part 2: Transplantation of Organ and Tissue from the Living**

**Question 16:**

**- Should the scrutiny of live transplants in Scotland be extended to cover cases where the donor and recipient are genetically related? If so, would this remove the current need for related donors to prove their relationship by genetic blood testing? Would it be possible not to make such a change in Scotland if it is being implemented in the rest of the UK?**

**Scottish Council on Human Bioethics Response:**

Yes, the SCHB agrees that the scrutiny of live transplants in Scotland should be extended to cover cases where the donor and recipient are genetically related. This would then address any possible undue pressures amongst family members.

**- Should the role of the Inspectorate for the rest of the UK be extended to Scotland for these purposes, or should a separate body be created in Scotland to take on this responsibility?**

**Scottish Council on Human Bioethics Response:**

At present in Scotland and the rest of the UK, if the potential donor is not genetically related to the recipient, the donation of an organ cannot take place until approval has been obtained from the Unrelated Live Transplant Regulatory Authority (ULTRA).



ULTRA is a cross-border public authority in terms of the Scotland Act 1998. Members of ULTRA scrutinise applications for live transplants to satisfy themselves that the parties are aware of the nature and risks of the procedure, that consent is being given freely without pressure being put on the donor, that no payment (other than re-imburement of expenses) is being made to the donor, and that the donor is aware that he or she is entitled to withdraw consent at any time.

In England and Wales, it is proposed that ULTRA would cease to exist as a separate body, with its extended functions being absorbed into those of the Inspectorate for Organs and Tissue for Human Use. In this respect, the SCHB considers that the role of the Inspectorate for the rest of the UK should be extended to Scotland for certain purposes.

**- Should paired and altruistic live donation be possible in Scotland?**

**Scottish Council on Human Bioethics Response:**

Since live kidney donation could be increased by paired donation, the SCHB notes that this procedure should be considered for any new legislation. Two potential pairs, hampered by blood group incompatibility, would then be able to exchange kidneys between pairs (for example, donor A, who is incompatible with recipient A, gives to recipient B, and donor B gives to recipient A).

The possibility of ‘altruistic’ donation, where a member of the public expresses a wish to donate a kidney to the national pool of potential recipients should also be taken into account after (1) providing extensive counselling to the potential donor and (2) obtaining informed consent.