

## **Consultation on Organ and Tissue Donation and Transplantation RESPONDENT INFORMATION FORM**

**Please Note** this form **must** be completed and returned with your response.

Are you responding as an individual or an organisation?

### **Organisation**

Full name or organisation's name: **Scottish Council on Human Bioethics**

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The Scottish Government would like your permission to publish your consultation response.

Please indicate your publishing preference:

### **Publish response with name**

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

**Yes**



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**Date: 14 March 2017 – Scottish Government**

**Consultation: *Organs and Tissue Donation and Transplantation***

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

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-religious registered Scottish charity composed of doctors, lawyers, biomedical scientists, 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 resolution 217A (III) on the 10<sup>th</sup> of December 1948.

The SCHB's response can be shared internally with other Scottish Parliament policy teams who may be addressing the issues discussed. They may contact the SCHB again in the future and the SCHB gives permission to do so.

The SCHB is very grateful to the Scottish Government for this opportunity to respond to the consultation on ***Organ and Tissue Donation and Transplantation***. It welcomes the Government's intention to promote public consultation, understanding and discussion on this topic.

**Executive Summary of the SCHB's response**

A significant amount of confusion has arisen with the definitions of the opt-in and opt-out systems in the Scottish Government consultation document entitled ***Organ and Tissue Donation and Transplantation***. Indeed, it is misleading to state that only an opt-in system exists in Scotland.

Because of this, the Scottish Council on Human Bioethics' (SCHB) will define the following terms as:

**Opt-in systems:** Legal systems enabling persons to instruct that their organs be removed for transplantation after death (for example, by carrying a donor card, informing relatives or joining a register) while the organs from all those, who have not left such instructions, cannot be removed.

These include:

- **Soft opt-in systems** whereby nearest relatives have a final say as to the removal of organs.
- **Hard opt-in systems** whereby nearest relatives do not have a final say as to the removal of organs.

**Opt-out systems:** Legal systems enabling persons to instruct that their organs not be removed for transplantation after death (for example, by carrying a refusal card, informing relatives or joining a register) while the organs from all those, who have not left such instructions, can be removed.

These include:

- **Soft opt-out systems** whereby nearest relatives have a final say as to the removal of organs.<sup>1</sup>

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<sup>1</sup> In the Scottish Government consultation document it is stated that a soft opt-out system "is a system of organ and tissue donation, also known as a deemed consent (or authorisation) system. A soft opt out system starts from the assumption that most adults can be a donor when they die unless they have stated that they do not wish to donate, but it normally allows for the family's views to be taken into account in some way." Scottish Government, *Organ and Tissue Donation and Transplantation*, 2016, p. 40.

- **Hard opt-out systems** whereby nearest relatives do not have a final say as to the removal of organs.

Using the above definitions, Scotland already has a form of soft opt-out system alongside its soft opt-in system. Indeed, when the **Human Tissue (Scotland) Act 2006** was being prepared, a specific provision was deliberately included in order to create a scheme whereby both the opt-in and opt-out systems would exist together for the removal of organs from a deceased person for transplantation. In other words, in Scotland there is both a:

- (1) Soft opt-in system (though nearest relatives may significantly add to the number of body parts being donated after death, without the informed consent of the deceased person, in conformity with Section 7 of the Act).
- (2) Soft opt-out system, similar to the Spanish system, when no prior wishes of the deceased person are known. Indeed, Section 7 (1) of the **Human Tissue (Scotland) Act 2006** states that if the nearest relative has no actual knowledge of the adult's wishes and there is "*no authorisation by the adult ... of removal and use of any part of the adult's body for transplantation, the nearest relative of the deceased adult may ... authorise the removal and use of any part*". This was confirmed by a Scottish Executive Press Release on the 30<sup>th</sup> of November 2005 presenting the new **Human Tissue (Scotland) Act 2006** which explained: "*These changes will make the legislation [in Scotland] similar to the way in which Spanish [soft opt-out] law is put into effect.*"<sup>2</sup>

Basically the present Scottish system of obtaining organs is the one that would provide the greatest number of organs without having to go down the road of a hard opt out system (with closest relatives having no say if a patient has not registered their opposition to donating organs) which most opt-out countries do not accept since it is considered unduly traumatic for relatives.<sup>3</sup>

In Scotland, just over 40% of the population are on the organ donor register, though over 90% of Scottish people support organ donation.<sup>4</sup> This reflects a difference between good intentions and actual decisions. It should be noted, however, that the principle of informed consent in medical ethics does not relate to intentions but decisions.

The SCHB is extremely concerned about the potential for serious mistakes resulting from the possibility of a nearest relative authorising the removal of body parts from a deceased person who has not left any specific instructions. This is because there is no certainty that the decisions of a nearest relative are a true reflection of the wishes of the person at the time of his or her death. As a result, the SCHB notes that an opt-out system (also known as a deemed consent system) cannot generally be defined as an appropriate consent/authorisation system for all those from whom organs<sup>5</sup> may be removed for transplantation and, accordingly, the SCHB considers any opt-out system to be ethically problematic.

The SCHB also believes that the opt-out system could lead to an undermining of public confidence in the transplantation system thereby eventually reducing the number of available organs. This is because it may erode the relationship of trust between health care professionals and the patient as well as undermine the principle of informed consent.

As the Scottish Government 2016 consultation document correctly points out:

*"[A] model based on "deemed" authorisation leads to people becoming donors when they actually would not have wanted to donate. This could risk being viewed by some as the state taking people's organs, rather than people actively choosing to give them. Any such perception could lead to a loss of trust in the NHS and the system more widely, which might actually lead to an increase in numbers of people*

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<sup>2</sup> 20<sup>th</sup> November 2005, <http://www.scotland.gov.uk/News/Releases/2005/11/30110629>

<sup>3</sup> An example of the anguish caused by going down the road of hard opt-out system was experienced in Singapore in 2007. Scuffle for organs sparks donor debate in Singapore – Reuters – 28.2.07 – <http://www.reuters.com/article/latestCrisis/idUSSIN173241>

<sup>4</sup> Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p.11.

<sup>5</sup> Subject to legal confirmation, this could also include ovarian tissue.

*choosing to opt out. It could also lead to conflict with families, which would be likely to put Specialist Nurses for Organ Donation, Tissue Donor Co-ordinators and doctors in a very uncomfortable position and make it difficult for them to gather sufficient information from the family about the patient's lifestyle to be reassured the organs or tissue will be safe to transplant.*"<sup>6</sup>

Moreover, 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 or her 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 include a procedure after death under the spirit of the law.

The SCHB would also like to obtain answers to the following questions:

**1. What is the level of awareness of the opt-out systems amongst the general population in countries, such as Wales and France, where such a system is already in place (or even in Scotland where a soft opt-out system has been in place since 2006)?<sup>7</sup>**

**2. What is the level of correct decisions being made by nearest relatives of an individual concerning his or her wishes relating to organ donation in Scotland?<sup>8</sup>**

In addition, the SCHB would like to examine whether the proposed change in the Welsh system will be effective in increasing the donation rate. This only came into force on the 1<sup>st</sup> of December 2015 and it is likely to take several years to see any effects.

So far, preliminary figures from Wales indicate that the opt-out system in place is not really providing a lot more organs:<sup>9</sup>

Total Organs Transplants in Wales

<b>2014/15:</b>	173
<b>2015/16:</b>	214
<b>First 9 month of 2016/17:</b>	138

The SCHB believes that it would be inappropriate support a soft opt-out system that may not provide real advantages whilst compromising the concept of informed consent and potentially having a negative impact on the doctor-patient relationship.

Finally, the SCHB would like to see Section 7 of the present **Human Tissue (Scotland) Act 2006** completely removed and re-written in order to prevent the current soft opt-out system in Scotland. Indeed, the SCHB believes that it is unlikely that (1) everybody in Scotland will be aware of the soft opt-out system in place and (2) nearest relatives could always appropriately reflect the wishes of the deceased.

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<sup>6</sup> Scottish Government, Organ and Tissue Donation and Transplantation, 2016, p. 22.

<sup>7</sup> In Hungary, for example, the opt-out system has been in force since 1998. However, in 2003, only 42% of the general public knew about the legal regulation.

<sup>8</sup> Recent statistics. 46% of families refuse donation because the relatives wishes are unknown (The Herald 17 No. 2015). Rate of family refusal are on the increase. It may be that proxies and nearest relatives are very bad at substituting judgement for others and that often only a random chance existed of making the same decision. Indeed, conference reports showed that spouses who had not discussed organ donation between them, mis-assumed the real wishes of their partner with respect to organ donation at a level of nearly 50%.

<sup>9</sup> NHS Blood and Transplant. Organ donation and transplant activity Wales. Jan 2017. <https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1518/wales.pdf>.

## Scottish Council on Human Bioethics Response to the Questions

### Question 1 – what do you think of the principle of a soft opt out system for Scotland?

- ~~I support the principle of a soft out system in Scotland~~  
- The SCHB does not support the principle of a soft opt out system

The SCHB very much supports the consideration of new ways to increase the number of organs available for transplantation in Scotland in order to allow more people to benefit from life-saving and life-changing transplants.

However, the SCHB cannot support the principle of a soft opt-out system in Scotland.

This is because the SCHB notes that an opt-out system cannot generally be defined as an appropriate consent/authorisation system for all those from whom organs may be removed for transplantation.

Opt-out systems whereby persons have to register their opposition to donated organs are often characterised as ‘presumed or deemed consent’ systems. However, the independent **UK Organ Donation Taskforce**, which was established by the UK Department of Health, indicated in its 2008 report entitled ‘*The Potential Impact of an Opt Out System for Organ Donation in the UK*’ that:

*“‘presumed consent’ is something of a misnomer in medical care because consent is in fact an active process in which permission is given by a patient for a procedure to be carried out on their body, thereby avoiding any possibility of clinical staff being guilty of an assault on the patient. Should a patient lack capacity and be unable to give consent for vital invasive procedures, doctors act on their judgement of the patient’s ‘best interests’, not on ‘a presumption’ of consent.”*

#### **Additional Concerns**

In Scotland, just over 40% of the population are on the organ donor register, though over 90% of Scottish people support organ donation.<sup>10</sup>

In this regard, questions can be asked relating to the reasons for this discrepancy and whether it should be respected as reflecting a difference between good intentions and actual decision making. This is a difficult question since the principle of informed consent does not relate to intentions but decisions.

Of course, citizens of a country are deemed to be aware of all enacted legislation even though this may be impossible in practice. But transplantation legislation is significantly different to other parts of the law since it relates to the human body of the individual person as such.

In addition, the SCHB is concerned about the manner in which an opt-out system reconceptualises the principles behind organ donation. It believes that donation should be a gift, an idea that is helpful both for the grieving families and the recipients of body parts.

By reframing the question surrounding donation, it redefines that relationship. Ms Joyce Robins, writing on behalf of Patient Concern, was stated as saying in 2008 that “*Presumed consent would turn us from volunteers into conscripts - unless we register as conscientious objectors ... Such a system would make the term ‘donation’ redundant. A donation is something freely gifted, not taken by default*”.<sup>11</sup>

This is also reflected by the General Practitioner, Dr. Margaret McCartney, who indicated in 2017 in the British Medical Journal “*A forced, presumed, or expected gift is not a gift. A striking feature of families who have allowed donation has been the desire to help others and the feeling that some shred of good has come out of their profound loss. If the sum of free will to donate is decreased, how can this benefit be realised to the same extent?*”<sup>12</sup>

The SCHB agrees with these statements and maintains that the donation of body parts should be motivated by a spirit of solidarity and altruism.

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<sup>10</sup> Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p.11.

<sup>11</sup> House of Lords, European Committee, Increasing the supply of donor organs within the European Union, Vol. 1: Report, 2008, The Stationery Office, p. 59.

<sup>12</sup> Margaret McCartney, When organ donation isn’t a donation, BMJ 2017; 356 doi: <https://doi.org/10.1136/bmj.j1028>

The SCHB is also very concerned that over the five year period 2008-2013, in Scotland, 62% of donations have come from donors who were not on the register at the time of their death. In these cases, it was the nearest relatives who gave the authorisation to donate organs.<sup>13</sup> Many of these would have had no actual knowledge whether the deceased was willing or unwilling to donate body parts after his or her death.

As a result, the SCHB believes that only an opt-in rather than an opt-out system is ethically appropriate.

**Question 2 – are there any changes you would make to the current ‘opt in’ authorisation system, other than moving to opt out?**

The SCHB notes that this question is misleading since the current Scottish scheme includes both a soft opt-in and a soft opt-out system.

Thus, because of its concerns relating to soft opt-out systems, it would like to see the current **Section 7** of the **Human Tissue (Scotland) Act 2006** completely removed and replaced with wording enabling only an opt-in (and not an opt-out) system of organ donation in Scotland.

This is in line with the 2008 Independent Report from the UK Organ Donation Taskforce which indicated that:

*“[After] examining the evidence, the Taskforce reached a clear consensus in recommending that an opt out system should not be introduced in the UK at the present time. The Taskforce concluded that such a system has the potential to undermine the concept of donation as a gift, to erode trust in NHS professionals and the government and negatively impact on organ donation numbers. It would distract attention away from essential improvements to systems and infrastructure and from the urgent need to improve public awareness and understanding of organ donation. Furthermore, it would be challenging and costly to implement successfully. Most compelling of all, we found no convincing evidence that it would deliver significant increases in the number of donated organs.”<sup>14</sup>*

The SCHB also believes that **Section 7** of this Act 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)

The SCHB believes that a soft opt-out system could eventually lead to an undermining of public confidence in transplantation and thereby reduced the number of available organs. This is because it may erode the trust relationship between clinicians and patients as well as undermine the principle of informed consent.

**Question 3 – where someone has joined the Organ Donor Register (ODR) or indicated in another way that they wish to donate, what do you think should happen if the potential donor’s family opposes the donation?**

- ~~- medical staff should still proceed with the donation~~
- medical staff should not proceed with the donation

A lot more work should be undertaken to encourage nearest relatives to give authorisation for transplantation when they know that this was the clear wishes of the deceased.

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<sup>13</sup> A Donation and Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

<sup>14</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 34.

Over the last five years the number and proportion of people in Scotland on the NHS Organ Donor Register has increased markedly – from 29% to over 41% at the end of 2012/13. Amongst the UK countries, Scotland now has the highest proportion of its population on the Register.<sup>15</sup>

The SCHB believes that there is still a lot to be done to increase the opt-in organ donation rate. It notes that Ms. Anne McTaggart's MSP's 2014 consultation document on the subject indicated that in Scotland:

*"[I]n up to 15% of cases, the opportunity to remove organs or tissues from people who were on the organ donor register is lost because their families refuse consent. In fact families refuse consent in around 43% of cases where donation would be possible. This refusal rate has not changed since 2008 and the UK has one of the highest refusal rates in the Western world. Spain in contrast has a refusal rate of less than 20%."*

The document adds that in the UK: *"Where the deceased's wishes are unknown the family refusal rate rises further to 57%".*<sup>16</sup>

Mr. Andrew Griffiths MP also indicated in 2014 in the UK Parliament that: *"In 2013, 94% of families in the UK agreed to an organ donation when their loved one was registered and had discussed their wishes with them. That fell away to 80% when they were on the register but had not discussed that with their family".*<sup>17</sup>

The 2008 UK **Organ Donation Taskforce** identified a number of barriers to donation, such as lack of awareness, laziness, unwillingness to think about death, a lack of trust in medical professionals and concerns about how donors are treated.<sup>18</sup> However, the SCHB believes that these are surmountable within the current legal system.

The Taskforce also indicated that *"The public engagement work undertaken suggests that numbers on the Organ Donor Register could be increased at a relatively modest cost through a more extensive publicity and engagement programme, perhaps akin to that for blood donation."*<sup>19</sup>

The 2008 **House of Lords** report noted that: *"Dr Rafael Matesanz, Director of the Spanish Organ Donation Office, argued strongly that organisational changes were much more important for increasing donation rates than presumed consent. "Opting in, opting out in my opinion means nothing". He explained that, although the presumed consent system had been in place since 1979, organ donation rates in Spain had remained low until changes to the organisational structure had started to be made in 1989."*<sup>20</sup>

The SCHB would like to see a follow up of all the recommendations presented by the 2008 **Organ Donation Taskforce** report entitled **Organs for Transplants** which indicated that these recommendations *"taken together, would create a structured and systematic approach to organ donation in the UK. The Taskforce believes their implementation would save the lives of at least 1,000 people each year and dramatically improve the quality of life for hundreds more, and for their families."*<sup>21</sup>

The SCHB also agrees that it would be preferable to invest in raising the profile of the Organ Donor Register and improving transplantation infrastructure instead of considering an opt-out system. It is of the opinion that a system that maintains the highest level of trust between the clinician and patient is the one that should be advocated for. In this regard, the 2008 UK **Organ Donation Taskforce** noted that:

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<sup>15</sup> A Donation and Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

<sup>16</sup> <http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-441/organ-donationand-transplants>

<sup>17</sup> Andrew Griffiths, Hansard, 17 Jun 2014 : Column 3WH-4WH, <http://www.publications.parliament.uk/pa/cm201415/cmhansrd/cm140617/halltext/140617h0001.htm>

<sup>18</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 20-21.

<sup>19</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 32.

<sup>20</sup> House of Lords, European Committee, Increasing the supply of donor organs within the European Union, Vol. 1: Report, 2008, The Stationery Office, p. 59

<sup>21</sup> Organ Donation Taskforce, Organs for Transplants, 2008, UK Department of Health, p. 52.

*“A system of decision making which is based on respecting the known wishes of the patient is the one that is most likely to maintain the integrity of the relationship between doctors and patients and between doctors and the wider public, and maintain trust and confidence in the donation system.”<sup>22</sup>*

According to the intensive care society’s survey, intensivists are evenly split as to whether an opt out system should be introduced, but the strength of feeling among those who are opposed is considerable. The Taskforce also noted that:

*“The Clinical Working Group of the Organ Donation Taskforce heard from a number of clinicians from intensive care (where the majority of deaths leading to donation occur) who were persuasive in articulating the view that a presumption of consent might make families feel that they were being pressured and erode the relationship of trust between clinician and family.”*

Adding that:

*“The concept of a gift freely given is an important one to both donor families and transplant recipients. The Taskforce feels that an opt out system of consent has the potential to undermine this concept”.<sup>23</sup>*

**Question 4 – if there was a soft opt out system, what do you think of the proposed checks set out in step 2 (on pages 14 to 15)?**

- ~~–these are sufficient to decide if a donation can be deemed to be authorised~~
- these are not sufficient to decide if a donation can be deemed to be authorised
- ~~–don’t know~~

The SCHB does not believe that high profile awareness-raising campaigns surrounding opt-out systems are possible long term. Even at present, Scottish people are unaware that their organs can be used for transplantation, even though they have not expressed any wish about the matter, if their nearest relatives give authorisation. The presumption is that any communication strategy would be a relatively short term project, and the necessary information is unlikely to continue at the high level of impact that would be required for the future.

In this regard, the SCHB’s concerns also lie with the more vulnerable members of Scottish society who may be unaware of the opt-out system in place.

These concerns echo the **2008 Organ Donation Taskforce** report which indicated: *“with an opt out system, not registering may mean that someone’s organs are taken when they had serious objections to this happening.”*

Adding that:

*“Were an opt out system to be introduced, a communications strategy would need to be devised to ensure that all those people who wished to opt out entirely, or to opt out of the donation of particular organs or tissues, knew how to do so. In addition, communications would be needed to outline arrangements for special groups such as children, those lacking capacity and visitors to the UK. Consideration would need to be given to the information needs of ethnic minorities, those with English as a second language, and hard-to-reach groups, such as the homeless. The media campaign would need to be extensive both in its use of different forms of media and in its duration (over at least two years, prior to and after enactment of legislation). Such a campaign would require considerable resource (... with further reminder campaigns every few years and as new transplants become possible). The effectiveness of this campaign would need to be evaluated on a regular basis to identify any deficiencies. A lack of information would disadvantage those who wished to opt out but did not know how to do so. This might conceivably lead to legal challenge in the future.”<sup>24</sup>*

It is extremely difficult for absolutely everyone in Scotland to be aware of the system in place. For the notion of consent to be meaningful, the public must be duly informed as soon as persons reach the age of

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<sup>22</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 17.

<sup>23</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 17.

<sup>24</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 31.



decision making. However where surveys have been conducted in opt-out countries, these have revealed that the public is either unaware or does not understand the rationale of 'silence enables organs to be used for transplantation'.<sup>25</sup>

This means that 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 or her 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.

In paragraph 102 of the Explanatory Report of the **Additional Protocol to the European Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin**<sup>26</sup> it is indicated (under Organ and Tissue Removal from Deceased Persons) that:

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

This perspective was also acknowledged in the **Policy Memorandum of the Human Tissue (Scotland) Bill** in 2005, where in paragraph 22, it was indicated 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>27</sup>

The **UK Organ Donation Taskforce** also indicated in its 2008 report that:

*"The Human Tissues Authority's guidance is clear that consent is a positive rather than a passive process which equips the prospective donor with the information needed to make a decision. Therefore, the change from opt in to opt out for transplant purposes could risk undermining the ... consent provisions, which safeguard the rights of individuals or their families to be asked if tissue can be used for a variety of purposes. The Human Tissue Authority was very concerned that a change to the consent requirements for one activity could result in the destabilisation of the consent provisions for other activities."*<sup>28</sup>

It then noted that:

*"The [Ethics Working Group of the Organ Donation Taskforce] recognised that there were problems with the current system. It is hard to argue that signing the Organ Donor Register is an act of 'informed consent', as the term is more broadly understood, but it is clearly intended as an act of authorisation. If a person has not registered their wishes formally, in the absence of a clear conversation taking place, a family can only do their best to establish what someone would have wanted. If there is uncertainty, the family carry the responsibility for deciding what to do on an uninformed basis, which is unsatisfactory regardless of the choice they make.*

*Uncertainty about a potential donor's wishes is at the heart of difficulties with the current system, yet uncertainty could remain an issue with an opt out system. It may not be appropriate to assume that all those who have failed to opt out have no objection to becoming donors, given the real possibility of apathy and/or disorganisation preventing them signing the opt out register. The group was not convinced*

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<sup>25</sup> In Hungary, for example, the opt-out system, has been in force since 1998. However, in 2003, only 42% of the general public knew about the legal regulation. (Cf Szanto Zs et al: LAM 2004; 14(89):620-6 (article written in Hungarian), cited by Aniko Smudla MD, Katalin Hegedus Ph.D., Semmelweis University, Institute of Behavioural Studies, Budapest).

<sup>26</sup> *Organ Donation and Transplantation – SPICe Briefing – 1 June 2000:*  
[http://www.scottish.parliament.uk/business/research/pdf\\_res\\_notes/rn00-40.pdf](http://www.scottish.parliament.uk/business/research/pdf_res_notes/rn00-40.pdf)  
*Organ Donation – Experiences Internationally – SPICe Briefing – 16 June 2005 :*  
<http://www.scottish.parliament.uk/business/research/briefings-05/SB05-82.pdf>

<sup>27</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 22., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

<sup>28</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 18.

*that evidence of widespread support, as expressed in opinion surveys, could necessarily support a claim that all those who fail to opt out actively intend to donate.*

*To sum up, the group ... felt that an improved opt in system, or possibly even a system where people were required to make the choice to opt in or opt out, would provide a basis on which to proceed with a greater degree of certainty about an individual's wishes and would therefore be more acceptable.”<sup>29</sup>*

In this regard, the Taskforce noted that “some people are concerned that a proportion of the 10% to 35% of the population who would not have wished to donate their organs, but never got round to registering an objection, could mistakenly be considered as willing donors under an opt out system.”<sup>30</sup>

In the relatively rare cases where the person did not have any family or close friends – or at least none who were contactable within the necessary timeframe – then no donation should be considered.

**Question 4(a) - if you think these are not sufficient, what other checks would be needed (apart from those covered in questions 6 to 8 below)?**

The SCHB believe that a soft opt-out system is ethically problematic and cannot be seen as acceptable.

**Question 5 – in any opt out system, what do you think should happen if a deemed authorisation donation was likely to distress the potential donor's family?**

- ~~–the donation should still proceed~~
- the donation should not proceed
- ~~–don't know~~

Thought the SCHB believes that opt-out systems should not be implemented, soft opt-out system are better than hard opt-out systems.

**Question 6 – if there was a soft opt out system, what do you think about the categories of people set out under step 3 (pages 15 to 17) for whom explicit authorisation would still be needed from the person themselves or family member?**

- ~~–the categories above are sufficient~~
- ~~–the categories above are not sufficient~~
- ~~–don't know~~

The SCHB accepts that a nearest relative can authorise the removal of an organ for transplantation from the deceased only if:

- It is someone who, over a long period of time before his or her death, did not have capacity to take a decision on donation;
- It is a child under the age of 12 years old.

Because in these cases nobody really knows what the individual would have wanted, nearest relatives should base their decision on what they believe would be the wishes of their relative.

But the SCHB is very alarmed with the proposal that the organs from anyone who has been a resident in Scotland for at least 12 months before their death could be removed for transplantation if they have not left any wishes. Indeed, it is extremely unlikely that they would even be aware of the organ system in place after such a relatively short time. It is also less likely that the nearest relatives of foreigners could be contacted in time.

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<sup>29</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 15.

<sup>30</sup> UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 8.

**Question 6(a) – if these are not sufficient, why do you think this?**

Not relevant.

**Question 7 – in what circumstances do you think an adult should be viewed as not having the capacity to make their own decisions about donation and therefore should not be subject to any deemed authorisation provisions?**

An adult should be considered as not having the capacity to make their own decisions about donation on a case by case system and in the light of the *Adults with Incapacity (Scotland) Act 2000*.

Anyone who meets the criteria for a guardian or attorney in terms of the Adults with Incapacity Act could be seen as not having capacity. Capacity is task specific and it is a difficult concept. Even if a person does not need a guardian they could still lack capacity to decide on organ donation. Capacity can also fluctuate. Many people do not meet the criteria for the *Adults with Incapacity (Scotland) Act 2000* but still lack capacity from time to time to make many decisions. That is why the presumed opt-out system is so dangerous.

**Question 8 – under what age do you think children should only be donors with explicit authorisation?**

- under 12
- ~~-under 16~~
- ~~-under 18~~
- ~~-other (please specify)~~

The organs of children under the age of 12 should only be removed for transplantation with explicit authorisation from the nearest relative.

Children should only be able to consent to organ removal for transplantation above the age of 16.

**Question 9 – for children who are in care, what are your views on allowing a local authority which has parental responsibilities and rights for a child to authorise donation for the child if no parent is available?**

- they should be allowed to authorise donation of a child's organs or tissue in those circumstances
- ~~-they should not be allowed to authorise donation of a child's organs or tissue~~
- ~~-don't know~~

**Question 10 – in any opt out system, what provisions do you think should apply to the less common types of organs and tissue?**

- ~~-deemed authorisation provisions should only apply to the more common organs and tissue (kidneys, liver, pancreas, heart/heart valves, lungs, small bowel and stomach, tendons, skin, corneas, bone)~~
- ~~-deemed authorisation provisions should apply to all organs and tissue~~

The SCHB believe that a soft opt-out system or 'deemed consent' is ethically problematic and cannot be seen as an acceptable form of consent. It is also very concerned that, even at present, certain organs, such as ovaries and facial tissue can be legally transplanted if the deceased had not left any wishes.

The transplantation of reproductive tissue and cells should be prohibited.

**Question 11 – which tests do you think medical staff should be able to carry out on a donor before they withdraw life-sustaining treatment to check if their organs or tissue are safe to transplant, both where a patient's authorisation for donation is 'deemed', as well as where the donation is explicitly authorised:**

The SCHB believe that a soft opt-out system or 'deemed consent' is ethically problematic and cannot be seen as an acceptable form of consent.

Where donation was explicitly authorised by the deceased person, all the following tests should be possible if this person has agreed to them. This conforms to the principle of appropriate informed consent.

**a) Blood tests?** - for tissue typing to find a good recipient match, to detect any infections, such as HIV or Hepatitis, or for testing the patient's blood gases to check how well the lungs function;

- yes
- no
- don't know

**b) Urine tests?** - to check if the patient has any infections;

- yes
- no
- don't know

**c) X rays?** - to check for any undiagnosed medical problems;

- yes
- no
- don't know

**d) Tests on a sample of chest secretions?** - taken via a tube to test how well the lungs function. Chest secretions are often removed from patients in Intensive Care as part of their treatment to help make them more comfortable so would be removed anyway as part of their care – this would therefore involve testing samples of the secretions that have been removed;

- yes
- no
- don't know

**e) Tests on the heart such as an ECG (electrocardiogram) or ECHO (echocardiogram)19?** – these tests check if the heart is functioning well.

- yes
- no
- don't know

**Question 12 – if you answered no to some or all options in question 11, are there any circumstances when particular tests could be permitted?**

- if the person had previously made clear they wished to be a donor
- if the donor's family provided consent on the donor's behalf
- such tests should never be permitted before death

Currently in Scotland these tests are not required for organ donation after circulatory death as hearts are only donated by patients diagnosed as brain-stem dead. However, heart donation after circulatory death has been trialled in some hospitals in England and might potentially be extended to include some Scottish donors in future.

The SCHB would prefer to leave these questions to the medical experts in the field.

**Question 13 – where it is agreed a patient's condition is unsurvivable and it will not cause any discomfort to them, what do you think about medical staff being allowed to provide any forms of medication to a donor before their death in order to improve the chances of their organs being successfully transplanted, such as providing antibiotics to treat an infection or increasing the dose of a drug the patient has already been given?**

- ~~- they should be able to provide such forms of treatment~~
- ~~- they should be able to provide such treatment, but only where the donor's family provides consent~~
- they should not be able to provide any such treatment just to help the donation

The SCHB believes that no intervention should take place on a living patient just for the sake of preparing his or her organs for transplantation. This is not in the interest of this living patient, goes completely against good medical practice and should not take place.

**Question 14 – what do you think about allowing people to appoint one or more authorised representatives to make decisions for them?**

- ~~–this should be allowed~~
- this is not necessary
- ~~–don't know~~

The SCHB welcomes the new updated version of the NHS Organ Donor Register, which was officially launched in July 2015, extending the choices a person has about their organ donation wishes. As well as being able to record a decision to be an organ donor, the new Register will now, for the first time, enable people in Scotland to clearly record their choice not to be an organ donor.<sup>31</sup>

Because it is now possible for persons to register their wishes to donate or not to donate organs after their death, the appointment of one or more authorised representatives is no longer necessary and would just make the process more complicated and lengthy.

**Question 14(a) – if you think this should be allowed, in what circumstances do you think an authorised representative would be useful?**

The SCHB believes that it is not necessary for individuals to appoint one or more authorised representatives to make decisions for them.

**Question 15 – do you have any other comments which you think should be taken into account in relation to any Scottish opt out system?**

The SCHB is extremely concerned about the potential for serious mistakes resulting from the possibility of a nearest relative authorising the removal of body parts from a deceased person who has not left any specific expression of wishes.<sup>32</sup> This is because there is no certainty that the decisions of a nearest relative are a true reflection of the wishes of the person at the time of his or her death.

Even the Policy Memorandum of the draft *Human Tissue (Scotland) Bill* – when it was being discussed in 2005 – accepted that nearest relatives were *‘changing their mind with respect to what they believed were the wishes of the deceased person when these have not been communicated.’*<sup>33</sup>

In addition, the SCHB notes that nearest relatives are often poor at substituting judgement for another and that sometimes only a random chance may exist of making the same decision.

In Ms. McTaggart MSP’s 2014 consultation document on transplantation systems it also conceded that *“There is a risk the family may make a false statement about their knowledge of the deceased person’s wishes in order to give expression to their own view.”*<sup>34</sup>

Moreover, 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 50 of the ***Human Tissue (Scotland) Act 2006*** are aware of the wishes of the deceased person or even knew him or her when he or she was still alive.

The SCHB is even aware of a case where just a landlord of a deceased person in Scotland was asked to authorise the removal of organs for transplantation.<sup>35</sup>

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<sup>31</sup> New NHS Organ Donor Register launched, Scotland Health and Community Care, 09/07/2015, <http://news.scotland.gov.uk/News/New-NHS-Organ-Donor-Register-launched-1b17.aspx>

<sup>32</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

<sup>33</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

<sup>34</sup> Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p. 19.

<sup>35</sup> Information received by the SCHB in conversation with a Specialist Nurse for Organ Donation.

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 led to the scandal at Alder Hey Children's Hospital in Liverpool in the 1990s. 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.

This was, indeed, made possible by the wording of the legislation at the time with the old **Human Tissue Act 1961** – which covered all the UK except Northern Ireland - indicating in Section 1(2) that:

*“... the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body [for therapeutic purposes and purposes of medical education and Research] ... if, having made such reasonable enquiry 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 had not withdrawn it; or*

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

This means that the Alder Hey scandal came as a direct result of what was supposed to be a soft opt-out system in which silence represents authorisation. But this quickly became unethical when healthcare professionals did not make sufficient 'reasonable enquiries' with surviving relatives and when these relatives authorised the removal of organs without being aware of the wishes of the deceased.

In addition, as noted in Ms. McTaggart MSP's consultation document, the average annual cost of dialysis for a patient with kidney failure is £30,800 but a successful kidney transplant operation costs £17,000 and £5,000 thereafter.<sup>36</sup> Thus the **NHS Blood and Transplant** predicts that for every year a kidney transplant remains functional, the NHS saves £24,100 per patient.<sup>37</sup>

However, the SCHB is of the opinion that it is not because a procedure can save lives or a lot of money that it automatically become ethical. Other principles may have priority such as the concept of the inherent human dignity of a person and the system of informed consent.

**Question 16 – what do you think about providing Chief Medical Officer (CMO) guidance to encourage clinicians to refer almost all dying or recently deceased patients for consideration as a potential organ or tissue donor?**

- CMO guidance should be provided to encourage more referrals

~~-CMO guidance should not be provided~~

~~-other (please specify)~~

The SCHB believes that all hospital doctors should refer, if appropriate, any patient for consideration as an organ and/or tissue donor if they are expected to die in a critical care area and are under the age of 85.

This would assist hospitals to learn lessons for the future and address any issues identified locally, such as around lack of awareness of organ and tissue donation or misunderstandings about what constitutes a contraindication to donation.

**Question 17 – what do you think about making it a procedural requirement for clinicians to involve a specialist nurse for organ donation, tissue donor coordinator or another individual with appropriate training in approaches to families about donation, wherever that is feasible?**

- this should be a requirement

~~-this should not be a requirement~~

~~-don't know~~

The SCHB believes that the Chief Medical Officer's guidance could re-emphasise the importance of all hospital staff doing what they can to facilitate donation and encourage clinicians to always involve

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<sup>36</sup> [http://www.organdonation.nhs.uk/newsroom/fact\\_sheets/cost\\_effectiveness\\_of\\_transplantation.asp](http://www.organdonation.nhs.uk/newsroom/fact_sheets/cost_effectiveness_of_transplantation.asp)

<sup>37</sup> [http://www.organdonation.nhs.uk/newsroom/fact\\_sheets/cost\\_effectiveness\\_of\\_transplantation.asp](http://www.organdonation.nhs.uk/newsroom/fact_sheets/cost_effectiveness_of_transplantation.asp)

Specialist Nurses for Organ Donation or Tissue Donor Co-ordinators in approaches made to families about donation.

**Question 18 – do you think there are particular impacts or implications for any equalities groups from any of the proposals in this consultation, either positive or negative? If yes, please provide details.**

The SCHB is of the opinion that any changes in transplantation legislation is likely to have an impact on some specific provisions for children and adults who do not have the capacity to understand or make their own decisions about organ or tissue donation (likely to be those with serious disabilities). There may also be some implications for some people from minority ethnic groups if they do not have a good understanding of English, as well as those with visual or hearing impairments, in ensuring that they are sufficiently aware of the system in place for the removal or organs for transplantation.