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**Date: 12 October 2015 – Health and Sport Committee**

**Consultation: *Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill***

**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 Health and Sport Committee for this opportunity to respond to the consultation on the ***Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill***. It welcomes its intention to promote public consultation, understanding and discussion on this topic.

**Scottish Council on Human Bioethics Response**

In the following response, the terms being used will be defined as:

**Opt out systems:** Systems which enable health care professionals to remove organs from every adult who dies – unless a person has registered to opt out. These may include:

- **Hard opt-out systems** whereby organs can be removed even if relatives oppose the donation for a number of reasons. Example: Austria.
- **Soft opt-out systems** whereby organs are only removed when the closest relatives give their agreement at the time of death. This may happen even when closest relatives have no actual knowledge of the wishes of the deceased. Example: Spain.
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**Opt in systems:** Systems which enable health care professionals to only remove organs from persons who have opted into a register thereby making an explicit decision on the matter. These may include:

- **Soft opt-in systems** whereby organs can be removed though health care professionals may decide not to proceed if faced with opposition from relatives.
- **Hard opt-in systems** whereby organs may be removed even though closest relatives are opposed to organs being used for transplantation.

## Executive Summary of the SCHB's response

### Problems with the Present Scottish Legislative Position

Scotland arguably already has a *de facto* opt-out system. Indeed, the **Human Tissue (Scotland) Act 2006** has created a hybrid system between the opt-in (explicit consent) and opt-out (sometimes presented as presumed consent) systems for the removal of organs from a deceased person for transplantation. In other words, the proposed system in Scotland is of:

- (1) Informed consent for those who register their wish to donate a number of organs before death on the Organ Donor Registry or by carrying an organ donor card (though their nearest relatives may significantly add to this 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) A *de facto* soft opt-out system, similar to the Spanish system, when no prior wishes of the deceased person are known. Indeed, the general thrust of the present soft opt-out system in the **Human Tissue (Scotland) Act 2006** states that if 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” (using the words of the Scottish Act in Section 7(1)) if the relative has no actual knowledge of the adult's wishes. This is confirmed in the Scottish Executive Press Release on the 30<sup>th</sup> of November 2005 leading up to the **Human Tissue (Scotland) Act 2006** which indicated that a consultant Surgeon at Edinburgh Royal Infirmary Transplant Unit, John Forsyth, said: “*These changes will make the legislation similar to the way in which Spanish law is put into effect.*”<sup>1</sup>

In this regard, 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. It is 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>2</sup> Many of these would have no actual knowledge whether the deceased was willing or unwilling to donate body parts after his or her death.

Because of this, the SCHB believes that only an opt-in rather than an opt-out system is ethically appropriate. As a result, it would like to see the present **Section 7** of the **Human Tissue (Scotland) Act 2006** removed completely and replaced with wording enabling an opt-in system of organ donation.

### Question 1: Do you support the Bill?

#### Scottish Council on Human Bioethics Response

The Scottish Council on Human Bioethics (SCHB) very much supports the consideration of new ways to increase the number of organs available for transplantation in Scotland and recognises the compassionate aims of the Bill. However, it believes that the present legislation being proposed is ethically inappropriate and should be rejected.

Opt-out systems whereby persons have to register their opposition to donated organs are often characterised as ‘presumed 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.*”

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<sup>1</sup> 20<sup>th</sup> November 2005, <http://www.scotland.gov.uk/News/Releases/2005/11/30110629>

<sup>2</sup> A Donation and Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

*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.*<sup>3</sup>

The SCHB notes that what is characterised as a 'presumed consent' system cannot generally be defined as appropriate consent for all those from whom organs may be removed for transplantation. Because of this, the SCHB considers any opt-out system as ethically problematic. 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 too traumatic for relatives.<sup>4</sup>

The SCHB, however, 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>5</sup>

The SCHB is also concerned about how realistic successful communication strategies surrounding the new system (if enacted) are likely to be. The Bill mentions the projected budget for the dissemination of information about the new system. However, the presumption is that this 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 going forward into the future. The SCHB's concern would lie with the more vulnerable members of Scottish society and the likelihood of the continued active engagement with the system.

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 "*there are issues about recording the wishes of those who do not engage with the UK's institutions and systems, including those with limited capacity and hard-to-reach groups.*"<sup>6</sup>

It would be 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 have been duly informed as soon as persons reach the age of 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 gives consent'.<sup>7</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 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**

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<sup>3</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.11.

<sup>4</sup> An example of the anguish caused by going down the route 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>5</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>6</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.

<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. (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).

**Tissues of Human Origin**<sup>8</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>9</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>10</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>11</sup>

### **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>12</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.

In addition, the SCHB has concerns as to the manner in which the change in system would reconceptualise the principles behind body part 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, stated 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>13</sup>

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

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<sup>8</sup> *Organ Donation and Transplantation – SPICe Briefing – 1 June 2000:*  
[http://www.scottish.parliament.uk/business/research/pdf\\_res\\_notes/m00-40.pdf](http://www.scottish.parliament.uk/business/research/pdf_res_notes/m00-40.pdf)  
*Organ Donation – Experiences Internationally – SPICe Briefing – 16 June 2005 :*  
<http://www.scottish.parliament.uk/business/research/briefings-05/SB05-82.pdf>

<sup>9</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 22.,  
<http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

<sup>10</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.

<sup>11</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.

<sup>12</sup> Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p.11.

<sup>13</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.

**Question 2: Do you think the Bill (if enacted) would achieve its aim of increasing the number of organs and tissue made available for transplantation in Scotland? Please provide an explanation of your answer.**

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

The SCHB believes that the system could lead to an undermining of public confidence in the transplantation system and thereby reduced the number of available organs by eroding the trust relationship between the clinician and the patient and undermining the principle of informed consent.

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>14</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>15</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>16</sup>

The SCHB would like to examine whether the proposed change in the Welsh system will be effective in increasing the donation rate. This does not come into force until the 1<sup>st</sup> of December 2015 and it will take several years to see the effects. It believes that it would be inappropriate to change to a 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.

The 2008 UK **Organ Donation Taskforce** identified a number of barriers to donation – for example, lack of awareness, laziness, unwillingness to think about death, a lack of trust in medical professionals and concerns about how donors are treated.<sup>17</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>18</sup>

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<sup>14</sup> A Donation and Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

<sup>15</sup> <http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-441/organ-donationand-transplants>

<sup>16</sup> Andrew Griffiths, Hansard, 17 Jun 2014 : Column 3WH-4WH, <http://www.publications.parliament.uk/pa/cm201415/cmhansrd/cm140617/halltext/140617h0001.htm>

<sup>17</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>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. 32.

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>19</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>20</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:

“*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>21</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>22</sup>

**Question 3: Do you support the proposal of appointing a proxy? Please provide an explanation for your answer.**

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

The SCHB is extremely concerned about the potential for serious mistakes resulting from the possibility of a closest relative authorising the removal of body parts from a deceased person who has not left any specific expression of wishes.<sup>23</sup> This is because there is no certainty that the decisions of a closest relative are a true reflection of the wishes of the person at the time of his or her death.

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<sup>19</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>20</sup> Organ Donation Taskforce, Organs for Transplants, 2008, UK Department of Health, p. 52.

<sup>21</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>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> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

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>24</sup> In addition, the SCHB notes that proxies are often poor at substituting judgement for another and that sometimes only a random chance may exist of making the same decision.

Ms. McTaggart MSP’s 2014 consultation document on transplantation systems 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>25</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.

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.

**Question 4: Do you have any comments on the role of “authorized investigating persons” as provided for in the Bill?**

**Scottish Council on Human Bioethics Response**

No comment.

**Question 5: Is there anything in the Bill you would change? If yes, please provide details.**

**Scottish Council on Human Bioethics Response**

The SCHB would like to see the present legislation in Scotland reformed as to only enable the opt-in, explicit consent, system to be implemented. 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>26</sup>

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<sup>24</sup> Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

<sup>25</sup> Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p. 19.

<sup>26</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.