

SUBMITTING EVIDENCE TO A SCOTTISH PARLIAMENT COMMITTEE

DATA PROTECTION FORM

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| Name: | Dr. Calum MacKellar |
| Date: | 3 September 2018 |
| Organisation: (if required) | Scottish Council on Human Bioethics |
| Topic of submission: | Human Tissue (Authorisation)(Scotland) Bill |

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HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM [SCOTTISH COUNCIL ON HUMAN BIOETHICS]



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Date: 4 September 2018 – Scottish Parliament – Health and Sport Committee

Consultation: *Human Tissue (Authorisation) (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 10th 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 of the Scottish Parliament for this opportunity to respond to the consultation on the ***Human Tissue (Authorisation) (Scotland) Bill***. It welcomes the Committee's intention to promote public consultation, understanding and discussion on this topic.

Executive Summary of the SCHB's response

The **Policy Memorandum** of the ***Human Tissue (Authorisation) (Scotland) Bill*** states that "*Scotland currently has what can broadly be described as an opt-in system of deceased organ and tissue donation.*" Adding: "*The **Human Tissue (Authorisation) (Scotland) Bill** will amend the **Human Tissue (Scotland) 2006 Act**, to supplement existing authorisation provisions with the introduction of a soft opt-out system for deceased organ and tissue donation.*"¹

This, however, is a complete misrepresentation and misunderstanding of both the current system and of what is being proposed with the Bill. Indeed, Scotland already has a form of soft-opt out system under the *Human Tissue (Scotland) 2006 Act*.

Moreover, what is being proposed under the *Human Tissue (Authorisation) (Scotland) Bill* is actually a form of hard opt-out system for the most common organs (such as heart, lungs, kidneys, liver, eyes, pancreas) and not a soft opt-out system where relatives have a final say.

This also means that (1) important parts of the 2017 Scottish Government public consultation entitled *Organs and Tissue Donation and Transplantation together* and (2) any other public consultation relating to a soft opt-out system in Scotland have now become irrelevant to many parts of the *Human Tissue (Authorisation) (Scotland) Bill*. This is because this Bill actually proposes a hard opt-out system for the removal of most organs for transplantation.

¹Policy Memorandum, ***Human Tissue (Authorisation) (Scotland) Bill***, p. 11, [http://www.parliament.scot/Human%20Tissue%20\(Authorisation\)%20\(Scotland\)%20Bill/SPBill32PMS052018.pdf](http://www.parliament.scot/Human%20Tissue%20(Authorisation)%20(Scotland)%20Bill/SPBill32PMS052018.pdf)

In order to clarify the confused understanding of the different opt-in and opt-out systems in the proposed Bill, the following definitions will be used in the SCHB's response:

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.²
- **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 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) A *de facto* soft opt-in system in that nearest relatives can veto the express wishes of the deceased for his or her organs to be removed for transplantation after death. Moreover, nearest relatives may significantly add to the number of body parts being donated after death for research, education, training or audit, without the informed consent of the deceased person, in conformity with Section 7 of the **Human Tissue (Scotland) Act 2006**.
- (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 [still] ... authorise the removal and use of any part*". This was confirmed by a Scottish Executive Press Release on the 30th 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.*"³

But with the proposed **Human Tissue (Authorisation) (Scotland) Bill**, while the opt-in system would be retained, the opt-out system is developed so that when the deceased has left:

- (1) No express authorisation for the removal and use of any part of his or her body for transplantation, and
- (2) No opt-out declaration for the removal and use of a part of his or her body for transplantation,

Then the deceased is deemed to have authorised the removal and use of a part of his or her body for transplantation.

² 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.

³ 20th November 2005, <http://www.scotland.gov.uk/News/Releases/2005/11/30110629>

Furthermore, if no clear evidence exists that he or she was unwilling to donate his or her organs, nearest relatives would not have a final say as to the removal of commonly donated types of organ and tissue, such as heart, lungs, kidneys, liver, eyes, pancreas, small bowel, heart valves, tendons.

A form of a hard opt-out system would then exist (Section 7 of the Bill inserting new Section 6D in the Act).

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.⁴

In Scotland, just over 50% of the population are on the organ donor register, though over 90% of Scottish people support organ donation.^{5,6} 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.

Opt-out systems raise serious ethical difficulties in that it is impossible to be sure that all persons in a country are aware of the system in place. From the very limited information available concerning other countries where opt-out systems have been in place for some time, evidence shows that only a minority of the population are actually aware that their organs can be removed if they say nothing. To be sure, it is possible to question whether opt-out systems are actually using this situation to increase the number of organs available but the very fact that a change is being proposed from an opt-in system (where such a situation cannot take place) to an opt-out system (where it can) is significant. In a way, accepting an opt-out system could be seen as using a person's ignorance of the scheme to try to increase the number of organs for transplantation which could be considered as a form of deceit.

In the Scottish Government proposal, when a deceased person has not left any specific instructions, nearest relatives will only be asked to give their authorisation for less common types of organs and tissue for transplantation (such as the face, reproductive organs and limbs). But serious mistakes may then happen because there is no certainty that the decision of the nearest relative is 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 organs⁷ may be removed for transplantation and, accordingly, the SCHB considers any opt-out system to be ethically problematic.

This is confirmed by the new international requirements of the UK **Data Protection Act 2018** which implements the European Union's *General Data Protection Regulation* (GDPR). In this regard, the UK's Information Commissioner's Office indicated that consent now requires a positive opt-in.⁸ It also noted that Article 4(11) of the GDPR defines consent as: "*any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her*".

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 the Scottish Government 2016 consultation document correctly points out:

⁴ 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>

⁵ Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p.11.

⁶ BBC News, Half of Scots pledge to donate organs after their death, 1 August 2018, <https://www.bbc.co.uk/news/uk-scotland-45022265>

⁷ Subject to legal confirmation, this could also include ovarian tissue.

⁸ <https://ico.org.uk/media/about-the-ico/consultations/2013551/draft-gdpr-consent-guidance-for-consultation-201703.pdf>

“[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 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.”⁹

In a way, opt-out systems seek to increase the number of persons who can be considered as donors as a result of some people’s unwillingness to think about death, lethargy or some other reason for not making a decision. However, for a government to use, in such a way, a refusal to make an important decision may be considered irresponsible; it may even undermine the very manner in which it should encourage accountable citizenship.

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 are the numbers in the different categories of nearest relatives who authorised the removal of organs in the past years under Section 50 of the Human Tissue (Scotland) Act 2006?

(2) How many nearest relatives had no clear indications of the wishes of the deceased when they authorised the removal of organs for transplantation in the past years under the Human Tissue (Scotland) Act 2006?

(3) 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)?¹⁰

(4) 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?¹¹

The SCHB also notes that the different soft opt-out systems in place both in Wales (since December 2015) have not increased or had a conclusive effect on deceased organ transplantation rates.¹²

| Deceased Donors: (Individuals) | Wales | Scotland | Deceased Donor Transplants: (Number of Organs) | Wales | Scotland |
|---------------------------------------|--------------|-----------------|---|--------------|-----------------|
| 2013/14 | 54 | 106 | | 158 | 342 |
| 2014/15 | 60 | 98 | | 128 | 300 |

⁹ Scottish Government, Organ and Tissue Donation and Transplantation, 2016, p. 22.

¹⁰ 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. Szántó Zs et al: LAM 2004; 14(89):620-6 (article written in Hungarian, cited by Smudla A, Hegedüs K, Semmelweis University, Institute of Behavioural Studies, Budapest).

¹¹ 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%.

¹² NHS Blood and Transplant. Organ donation and transplant activity Wales and Scotland. <https://www.organdonation.nhs.uk/supporting-my-decision/statistics-about-organ-donation/>

| | | | | |
|---------|----|-----|-----|-----|
| 2015/16 | 64 | 99 | 168 | 332 |
| 2016/17 | 61 | 133 | 135 | 348 |
| 2017/18 | 74 | 102 | 137 | 375 |

It has always been doubtful that the different systems, themselves, could increase organ donation in contrast to the organisation structure. Spain is leading the world in deceased organ donation¹³ but as Dr. Matesanz, a past Director of the Spanish Organ Donation Office, argued: “*Opting in, opting out in my opinion means nothing*”.

He explained that, although the opt-out system had been in place since 1979 in Spain, organ donation rates had remained low until changes to the organisational structure had been made in 1989.¹⁴

The BBC also notes in 2017 that “*opt-out schemes don't always translate to increased organ donor rates. In Sweden, for example, such a scheme has been in force since 1996 and it remains one of the lowest-ranked countries for organ donation in Europe. Luxembourg and Bulgaria also have opt-out systems and low rates of organ donation... In France and Brazil, variations on a "presumed consent" system actually led to a decline in the rate of organ donation.*”¹⁵

It would, therefore, be inappropriate for the Scottish Parliament to support a soft opt-out system that may not provide real advantages to patients whilst compromising the concept of informed consent - a system that could even undermine public confidence in the transplantation system and eventually reduce the number of available organs.

An example of the dangers that may arise when important decisions are made by others on what they ‘deem’, ‘assume’ or ‘presume’ are the wishes of a 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 or when these relatives authorised the removal of organs without being aware of the wishes of the deceased.

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.

Alternatives to the soft opt-out system

¹³ R. Matesanz et al. "How Spain reached 40 deceased organ donors per million population." *American Journal of Transplantation*; Published Online: 9 January 2017.

¹⁴ House of Lords, European Committee, Increasing the supply of donor organs within the European Union, Vol. 1: Report, 2008, The Stationery Office, p. 59.

¹⁵ BBC News, Organ donation: Does an opt-out system increase transplants? 10 September 2017, <https://www.bbc.co.uk/news/health-41199918>.

The SCHB believes a lot more can be done to increase the number of organs available for transplantation using alternative and more ethical measures. These include:

- Continuing to encourage all Scottish persons to register their willingness to donate organs after death.
- Encouraging nearest relatives to discuss organ donation after death with each other.
- Encouraging nearest relatives to give authorisation for transplantation when they know that this was the clear wishes of the deceased.
- Making sure that every appropriate organ which can be used for transplantation is used.
- Making sure that every appropriate donor of organs after death is considered for donation.
- Developing xenotransplantation and the use of organs from appropriate animals.

Question 1:

What do you think are the key strengths and weaknesses of the proposals to introduce 'deemed authorisation' for those who have not made their wishes on organ donation known?

Scottish Council on Human Bioethics Response

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 believes that it will not increase the number of organs available while noting 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."

1. Additional Concerns

1.1. Difference between intentions and decisions

In Scotland, just over 50% of the population are on the organ donor register, though over 90% of Scottish people support organ donation.^{16,17}

¹⁶ Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p.11.

¹⁷ BBC News, Half of Scots pledge to donate organs after their death, 1 August 2018, <https://www.bbc.co.uk/news/uk-scotland-45022265>

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.

1.2. Organ donation should be a gift

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*”.¹⁸

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?*”¹⁹

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

1.3. Many nearest relatives do not know the wishes of the deceased

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.²⁰ This is because there is no certainty that the decision of a nearest relative is a true reflection of the wishes of the person at the time of his or her death.

In 2009, only 40% of all EU citizens had raised the issue of organ donation and transplantation with their family, compared to 59% who had never broached this subject. In the UK, the proportion of respondents who reported discussing this topic with their family actually dropped from 43% in 2006 to 37% in 2009.²¹

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*.”²²

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*.”²³

¹⁸ House of Lords, European Committee, Increasing the supply of donor organs within the European Union, Vol. 1: Report, 2008, The Stationery Office, p. 59.

¹⁹ Margaret McCartney, ‘When organ donation isn’t a donation’, BMJ 2017; 356; doi: <https://doi.org/10.1136/bmj.j1028>

²⁰ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

²¹ European Commission. TNS Opinion and Social. Organ donation and transplantation. In: Special eurobarometer 333a/Wave 72.3. Brussels: The European Commission, 2010, p.7; http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_333a_en.pdf

²² Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

The SCHB noted 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.²⁴ But many of these relatives would have had no actual knowledge whether the deceased was willing or unwilling to donate body parts after his or her death.

The **Scottish Parliament Information Centre** (July 2018) further indicated that information relating to the certainty of those who did authorise donation is not collected as a matter of routine in Scotland. It also mentioned that, according to the **National Potential Donor Audit**, where someone has not registered their wishes and the family refused donation, 15% of these refusals were based on the nearest relatives being unsure about the deceased's wishes.

In addition, the audit found that when it was clear that the patient was on the Organ Donor Register (ODR), the consent rate when the family were approached for authorisation was 90% compared to 51% when the patient's ODR status was unknown. This disparity may indicate a higher level of uncertainty of the deceased's wishes.²⁵ These results also confirm that up to 51% of nearest relatives may not have known the wishes of the deceased when they authorised the removal of organs for transplantation.

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.²⁶

According to the **Scottish Parliament Information Centre** (July 2018), the numbers in the different categories of nearest relatives who authorised the removal of organs in the past 2-3 years under Section 50 of the **Human Tissue (Scotland) Act 2006** is not routinely collected in Scotland.

The **Scottish Parliament Information Centre** (July 2018) also indicated that it had searched medical research literature for one-off studies which tested family members knowledge of each other's wishes on donation but could not find anything.

Finally, recent research in 2018 has indicated that when relatives have to decide what to do, they are more likely to veto the organ donation in an opt-out system if they cannot be sure what the underlying wishes of the deceased were. As such, the study found that: *"ambiguous signals of underlying preference that are attached to ... opt-out systems contribute to families' veto decisions as compared with active choice systems (opt-in ...), which are substantially better at signalling intent than are passive ones."*²⁷

1.4. Opt-out systems may reduce trust between patients and their physicians

The SCHB 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. 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."*²⁸

²³ Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p. 19.

²⁴ A Donation and Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

²⁵ Source: National Potential Donor Audit

²⁶ Information received by the SCHB in conversation with a Specialist Nurse for Organ Donation.

²⁷ Lin Y., Osman M., Harris AJL., Read D., Underlying wishes and nudged choices, *J Exp Psychol Appl.* 2018 Aug 16. doi: 10.1037/xap0000183.

²⁸ 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.

According to the UK **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".²⁹

1.5. Ineffective promotion of the organ system in place

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 wishes 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 required for the future. In this regard, the SCHB is concerned about 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."³⁰

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 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'.³¹

The **Scottish Parliament Information Centre** (July 2018) contacted the Welsh Assembly Government who indicated that it had gathered information on levels of awareness in Wales before and

²⁹ 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.

³⁰ 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.

³¹ 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).

after the law was passed in 2015. This showed that in 2012, prior to the Act, 58% of Welsh people were aware that there was a possible change to the law. By 2015, after the law came into effect, this had risen to 74% and in March 2016 it was at 82%, later falling back to 76% in June 2016. This resulted in the Welsh Government concluding that publicity around the law needed to be maintained.

Evidence from across Europe in 2009 has shown a very poor understanding of existing donor registration policies. Only 28% of EU citizens were aware of laws governing the donation and transplantation of organs in their country. By contrast, 68% of people surveyed said they did not know such laws. In the UK, only 23% of the population were aware of the laws in place in 2009 relating to donation and transplantation of human organs.³²

1.6. Opt-out systems may infringe human rights

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**³³ 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.”³⁴

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.”³⁵

It then noted that:

³² European Commission. TNS Opinion and Social. Organ donation and transplantation. In: Special eurobarometer 333a/Wave 72.3. Brussels: The European Commission, 2010, p.11-12;
http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_333a_en.pdf

³³ *Organ Donation and Transplantation – SPICe Briefing – 1 June 2000:*
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>

³⁴ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 22., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

³⁵ 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.

“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 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.”³⁶

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.”³⁷*

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.

1.7. The present Section 7 of the Human Tissue (Scotland) Act 2006 should be amended

The SCHB notes that 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.”³⁸

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.

³⁶ 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.

³⁷ 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.

³⁸ 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.

1.8. The Challenges of Cost Factors

As noted in Ms. McTaggart MSP's previous 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. Thus the **NHS Blood and Transplant** organisation predicts that for every year a kidney transplant remains functional, the NHS saves £24,100 per patient.³⁹ 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 becomes ethical. Other principles may have priority such as the concept of the inherent human dignity of a person and the system of informed consent.

2. Alternatives Recommendations

2.1. Encouraging nearest relatives to give authorisation for transplantation when they know that this was the clear wishes of the deceased.

Over the years, the number and proportion of people in Scotland on the NHS Organ Donor Register has increased markedly – from 29% at the end of 1997/98 to over 50% in July 2018. Amongst the UK countries, Scotland now has the highest proportion of its population on the Register with the UK average in March 2018 being 38%.^{40,41}

But 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 (through an opt-in system) of the deceased.⁴² The SCHB 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%"*.⁴³

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"*.⁴⁴

2.2. Encouraging persons to register their willingness to donate

The 2008 UK **Organ Donation Taskforce** identified a number of barriers to donation, such as lack of awareness, lethargy, unwillingness to think about death, a lack of trust in medical professionals and concerns about how donors are treated.⁴⁵ However, the SCHB believes that these are surmountable within the current legal system.

³⁹ http://www.organdonation.nhs.uk/newsroom/fact_sheets/cost_effectiveness_of_transplantation.asp

⁴⁰ A Donation and Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

⁴¹ BBC News, Half of Scots pledge to donate organs after their death, 1 August 2018, <https://www.bbc.co.uk/news/uk-scotland-45022265>

⁴² For a good review see: P. Kumar Prabhu, Is presumed consent an ethically acceptable way of obtaining organs for transplant?, *Journal of the Intensive Care Society*, 21 May 2018, <https://doi.org/10.1177/1751143718777171>.

⁴³ <http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-441/organ-donationand-transplants>

⁴⁴ Andrew Griffiths, Hansard, 17 Jun 2014 : Column 3WH-4WH, <http://www.publications.parliament.uk/pa/cm201415/cmhansrd/cm140617/halltext/140617h0001.htm>

⁴⁵ 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.

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.*”⁴⁶

Research in 2018 indicates that 66.1% of participants selected to opt-in to the donor register, 24.3% selected deemed consent, and 9.4% selected opt-out/not sure. Emotional barriers, notably fears surrounding bodily integrity, were significantly elevated in participants who selected opt-out/not sure. Increasing the salience of emotional barriers reduced donor intentions in the opt-out/not sure group. However, dispelling organ donation myths did not increase intention within this group.⁴⁷

2.3. Improve transplantation organisation structure

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.*”⁴⁸

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.*”⁴⁹

Moreover, according to a 2018 **NHS Blood and Transplant’s** own impact assessment report mentioned in *The Guardian*, hospitals are so short of transplant surgeons and specialist nurses that lives could be lost. This is because teams of organ retrieval specialists in England are already under “extreme stress” and understaffed transplant centres are struggling to keep up with existing demand.⁵⁰

2.4. Health Care Professionals should refer almost all dying or recently deceased patients for consideration as a potential organ or tissue donor

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.

The SCHB believes that all hospital staff should do what they can to facilitate donation and encourage clinicians to always involve Specialist Nurses for Organ Donation or Tissue Donor Co-ordinators in approaches made to families about donation.

3. Other Comments

3.1. Nearest relative should only be able to authorise the removal of an organ for transplantation in exceptional conditions

⁴⁶ 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.

⁴⁷ Miller, J. , Currie, S. and O’Carroll, R. E. (2018), ‘What if I’m not dead?’ – Myth-busting and organ donation. *Br J Health Psychol*.

⁴⁸ House of Lords, European Committee, *Increasing the supply of donor organs within the European Union*, Vol. 1: Report, 2008, The Stationery Office, p. 59

⁴⁹ Organ Donation Taskforce, *Organs for Transplants*, 2008, UK Department of Health, p. 52.

⁵⁰ Denis Campbell, *NHS opt-out transplant policy at risk due to cuts and staff stress*, *The Guardian*, 15 July 2018, https://www.theguardian.com/society/2018/jul/15/nhs-opt-in-organ-transplant-policy-at-risk-cuts-staff-stress?CMP=Share_iOSApp_Other

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 the person in question.

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

Anyone who meets the criteria for needing a guardian or attorney in terms of the *Adults with Incapacity (Scotland) Act 2006* could be seen as not having capacity.

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 problematic.

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.

3.2. Certain organs have special meaning

The SCHB is also very concerned that, even at present, certain organs, such as ovaries, reproductive organs and facial tissue can be legally transplanted if the deceased had not left any wishes. Moreover, the transplantation of reproductive tissue and cells should be prohibited.

3.3. Organ removal from non-residents

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.

Question 2:

What do you think are the key strengths and weaknesses of the plans for authorisation of pre-death procedures?

Scottish Council on Human Bioethics Response

Usage of the term 'pre-death procedure' is very unfortunate. Cutting the throat of a person may also be considered as a 'pre-death procedure' and suggestions already exist in bioethical literature concerning the harvesting of organs before death. A more appropriate terminology would be 'Preparatory procedures taking place before CDC death in the context of transplantation'.

It should also be made clear in the legislation, itself, that such procedures are never expected to shorten the life expectancy of the patient.

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;

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

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

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;

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

Question 3:

Do you have any other comments to make on the Bill?

Scottish Council on Human Bioethics Response

(1) In Part 2, Section 2: it is mentioned that Scottish Ministers will have to ‘promote’ information and awareness about how transplantation may be authorised and about the nature of pre-death procedures. The real problem, however, with the term ‘promote’ is that it is unclear and may even just represent the sending of leaflets to GP waiting rooms.

This is not sufficient to address the real problems of persons not being aware of the system. Already in Wales, a quarter of the population is unaware of the system in place in June 2016. This is unacceptable and cannot represent an appropriate system of organ removal.

(2) In Part 3, Chapter 2, Section 10-11: The SCHB notes that if the deceased has left:

- (1) No express authorisation for the removal and use of any part of his or her body for research, education and training and audit and quality assurance,
- (2) No opt-out declaration for the removal and use of the part of his or her body for research, education and training and audit and quality assurance, and
- (3) No opt-out declaration for the removal and use of the part of his or her body for transplantation,

Then the nearest relative may still authorize the removal and use for research, education and training and audit and quality assurance of any body part (common or excepted) from the deceased. But only if the relative has no actual knowledge that the deceased was unwilling for such excepted body-parts to be removed and used in such a manner (Section 11 of the Bill inserting new section 6H).

Again, this is considered to be completely unethical by the SCHB.

(3) The SCHB is extremely concerned that Section 7 of the new Bill in effect introduces a form of ‘**hard opt-out**’ system of organ removal in Scotland. This is because if a person has opted-in, opted-out or is ‘deemed’ to have left an authorisation for transplantation (by not stating any wishes) then the nearest relative could only stop certain organs being removed if they can produce concrete evidence that the deceased did not want them to be removed.

But this would create a situation where the views of nearest relatives could be ‘overridden’ by the decision of healthcare professionals to remove the organs for transplantation.

(4) 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. 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 of organs for transplantation.

(5) Finally, the SCHB wanted to indicate how challenging it has become to actually understand the Bill. It has become extremely difficult to follow all the amendments and the double negatives in the articles such

in Section 10 (2) which stated that: “The nearest relative of the adult may authorise the removal and use of a part of the adult’s body ... where ... the relative has no actual knowledge that ... the adult was unwilling for the part to be removed and used for transplantation”.

Such unclear provisions do not help the democratic process in any way.

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In the case *Petrova v Latvia 2014*, the applicant’s adult son died in a public hospital in Riga as a result of serious injuries sustained in a car accident. The applicant subsequently discovered that her son’s kidneys and spleen had been removed immediately after his death without her knowledge or consent. The Latvian Government argued that when close relatives were not present at the hospital, national law did not impose an obligation to make specific inquiries with a view to ascertaining whether there was any objection to organ removal and that, in such cases, consent to removal could be presumed. However, the European Court of Human Rights found that the way in which this ‘presumed consent system’ operated in practice in cases such as the applicant’s was unclear: despite having certain rights as the closest relative she was not informed – let alone provided with any explanation – as to how and when those rights could be exercised.⁵¹

In *Elberte v Latvia 2015*, the European Court of Human Rights heard the case of a death of the applicant’s husband in a car accident. Tissue was removed from his body during an autopsy at a forensic centre and sent to a pharmaceutical company in Germany with a view to creating bio-implants, pursuant to a State-approved agreement. When the body was returned to the applicant after the completion of the autopsy its legs were tied together. The applicant only learned of the removal of the tissue two years later, in the course of a criminal investigation into allegations of wide-scale illegal removal of organs and tissues from cadavers.

The Court rules that although Latvian law set out the legal framework for consenting to or refusing tissue removal, it did not clearly define the scope of the corresponding obligation or the discretion left to experts or other authorities in this regard. The Court noted that the relevant European and international materials on this subject attached particular importance to establishing the relatives’ views through reasonable enquiries. The principle of legality likewise required States to ensure the legal and practical conditions for implementation of their laws. However, the applicant had not been informed how and when her rights as closest relative could be exercised or provided with any explanation.⁵²

European Convention on Human Rights. Two cases are highly relevant here - *Petrova v Latvia in 2014* where it was argued that a lack of clarity in Latvian law about whether there was an obligation to inform or gain consent from close relatives prior to removing tissue or organs was a violation of Article 8 and *Elberte v Latvia* in 2015.

The court found a violation of Mrs Elbert’s right to privacy under Article 8. They also found that she had suffered degrading treatment under Article 3 due to the removal of her husband’s tissues.³⁰⁵³ Given what we noted above about relational autonomy, it was interesting to note that this case was not decided on the basis of family life protections under Article 8 but the focus instead on a private life³¹⁵⁴.

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⁵¹ <https://swarb.co.uk/petrova-v-latvia-echr-24-jun-2014/>

⁵² <https://swarb.co.uk/elberte-v-latvia-echr-13-jan-2015/>

⁵³ Neethu R (2016) ELBERTE v LATVIA: The To be or not to be question of Consent . Medical Law Review, Volume 25, 3, 1 August 2017, Pages 484–493

⁵⁴ Dove ES (2015) Elberte v Latvia:a curious case of tissue, relatives and the ‘right to private life’ The Motley Coat Blog of the Mason Institute. Available from:<http://masoninstitute.blogspot.com/2015/02/elberte-v-latvia-curious-case-of-tissue.html> [Accessed August 25 2018]

See: Albertsen, A (2018) Deemed consent: assessing the new opt-out approach to organ procurement in Wales. *J Med Ethics*;44:314–318 at p. 314 Available from <https://jme.bmj.com/content/medethics/44/5/314.full.pdf>