EXPLANATORY MEMORANDUM

The Human Tissue Authority Code of Practice 2015 on the Human Transplantation (Wales) Act 2013

This Explanatory Memorandum has been prepared by the Health and Social Services Group and is laid before the National Assembly for Wales in conjunction with the above statutory Code of Practice and in accordance with Standing Order 27.1 and 27.14.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Human Tissue Authority Code of Practice 2015 on the Human Transplantation (Wales) Act 2013. I am satisfied that the benefits outweigh any costs.

Mark Drakeford AM
Minister for Health and Social Services
September 2015

1. Description

The Human Transplantation (Wales) Act 2013 ("the 2013 Act") requires that the Human Tissue Authority[1] (HTA) prepare a Code of Practice ("the Code of Practice") to give practical guidance on the circumstances in which consent is deemed under section 4 of the 2013 Act.

The Code is a HTA document, so it is laid in English only. It will be produced in Welsh once all approvals are given. The National Assembly for Wales may approve or reject the Code but may not amend it. Any code drafted by the HTA also needs to be approved by the UK Parliament by negative resolution. Therefore, if approved by the National Assembly for Wales, the Code will be laid before Parliament on 12 October.

The Code will be used operationally from the introduction of deemed consent on 1 December 2015.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

The Committee's attention is drawn to the fact that the Code of Practice is part of a package of subordinate legislation to be made under the Human Transplantation (Wales) Act 2013. These comprise (the regulations which are the subject of this Explanatory Memorandum are shown in bold):

- The Human Transplantation (Appointed Representatives) (Wales) Regulations 2015 (these Regulations);
- The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015;
- The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015 and
- **The Human Tissue Authority Code of Practice 2015 on the Human Transplantation (Wales) Act 2013**

The above Regulations and Code of Practice are laid before the National Assembly for Wales at the same time for approval. A separate Explanatory Memorandum has been prepared for each instrument.

[1] The HTA is the regulator for organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. They also give approval for organ and bone marrow donations from living people. - See more at: https://www.hta.gov.uk/about-us#sthash.GLdIqjaq.dpuf

3. Legislative background

The Human Transplantation (Wales) Act 2013 comes fully into force on 1 December 2015.

The purpose of the 2013 Act is to change the way in which consent, for the purposes of transplantation, is to be given to organ and tissue donation in Wales. The 2013 Act introduced two concepts, “express consent” and “deemed consent”. It provides that in the absence of express provision in relation to consent, consent will be deemed to have been given in most cases. This means that, after death, a person’s consent will be deemed to have been given unless they had expressed a wish for or against donation, or appointed a representative to make the organ donation decision on their behalf.

There are several exceptions to deemed consent, including children; those who are not ordinarily resident in Wales; and those who lack capacity to understand the notion of deemed consent. In such cases, express consent (which has the same meaning as appropriate consent set out in the Human Tissue Act 2004 (“the 2004 Act”) will apply. It is also the case that if a family member or friend of long standing can provide information to show the deceased person objected to donation, then deemed consent will not apply. This involvement of family and friends in the discussion around organ donation is why the system is termed a “soft opt-out” system. In addition, consent will not be deemed in respect of so-called novel forms of transplantation or to living donation.

The 2013 Act amends sections 26 and 27 of the 2004 Act to require the HTA to prepare a Code of Practice to give practical guidance on the circumstances in which consent is deemed under section 4 of the 2013 Act.

4. Purpose and intended effect of the Code

The Code of Practice is made under section 26 of the Human Tissue Act 2004, as amended by section 15 of the Human Transplantation (Wales) Act 2013.

Section 26 of the 2004 Act provides that the HTA may prepare and issue Codes of Practice which give practical guidance to persons carrying on activities with the HTA’s remit and to lay down the standards expected in relation to the carrying on of such activities. A number of Codes have already been issued by the HTA under these provisions in relation to consent and the donation of solid organs for transplantation, as well as Codes relating to other matters, for example, in relation to post mortem examinations, disposal of relevant material and public display of body parts.

Section 15 of the 2013 Act amends section 26 and section 27 of the 2004 Act to also require the HTA to prepare a Code of Practice to give practical guidance on the circumstances in which consent is deemed under section 4 of the 2013 Act

The Code of Practice laid before the Assembly for approval therefore provides practical advice and guidance on the interpretation and implementation of the Human Transplantation (Wales) Act 2013. The Code of Practice is primarily intended for use by Specialist Nurses for Organ Donation (SNODs), other clinicians and professionals working in the transplantation sector in Wales. It may also be of assistance to clinicians in other areas and specialities, both in and outside Wales, as well as the public.

5. Consultation

Under section 26(5) of the 2004 Act, the HTA is required to undergo a consultative process before producing its Codes of Practice. The HTA carried out a process of consultation on the Code from 1 October 2013 until 23 December 2013. This included hosting events in Cardiff, Aberystwyth and Llandudno.

A wide range of stakeholders, both individuals and organisations, put forward their views, including clinicians, charities, faith organisations, professional bodies, and members of the public. A total of 85 responses were received.

The overall response to the Code was positive. Several useful suggestions were made for improvements to the Code which the HTA acted upon.

The key themes that emerged from the consultation were:

Accessibility of the Code – the majority felt it was easy to understand though some concerns were expressed about the length of the Code and whether lay people would understand it.

Structure - Respondents were content that the Code was laid out in a logical order, although there were some suggestions for reordering some of the content and clarifying some of the terms at earlier points.

Examples and case studies - The majority of respondents were content that the examples provided through out the Code were clear and helpful. It was suggested that additional case studies could be provided.

Seeking consent - The large majority of respondents were content that the Code makes clear from whom the SNOD would seek consent in cases where consent cannot be deemed. It was suggested that absolute clarity was required on the status of an appointed representative in making a decision in comparison to family members, especially when children are involved. It was also suggested that extra advice was required regarding situations where family members disagree over consent.

Evidence of deceased person's wishes regarding Organ Donation - The majority of respondents were content with the information provided in the Code regarding; who can provide evidence on behalf of the deceased, how the

SNODs assess the evidence, that the approach would work in practice, and that it followed other professional advice and guidance.

A number of general suggestions were received regarding additional information or advice which might be useful, including:

- Lightening the burden on grieving families to provide evidence that the deceased would not have wanted to be a donor, reiterating the language used regarding emotional impact on family and friends throughout the document, and reminding SNODs and clinicians of their duty of care for the bereaved.
- Providing clarity on; the role of the SNOD, the role of a medical Lasting Power of Attorney, the definition of "significant period" with regards to a patient lacking capacity, and the role of an Independent Mental Capacity Advocate for people without family or friends.
- Placing more emphasis on tissue donation throughout the Code.
- Explaining that organs might go to patients elsewhere in the UK, other than Wales.
- How a SNOD would deal with requests by family for direct donations.

The main issues which have been revised in the code are set out below. Changes were made to:

- Correct typographical errors, provide more detail, and clarify sections where some of the information may have been less clear.
- The order in which information was presented in order to provide an introduction, a section on practical advice and guidance, and a section on further relevant information.
- Clarify how a person can record their decision to either opt-in or opt-out on the NHS Organ Donor Register.
- Include additional examples of case studies which would be helpful to practitioners.
- Include a table has been which clearly explains when the list of relations is ranked in accordance with section 27(4) of the Human Tissue Act 2004, and when it is not.
- An explanation to provide assurance that all SNODs work within the decision making structures of NHS Blood and Transplant and do not make decisions in isolation.
- Further information was included on married 16 and 17 year olds to clarify the qualifying relationship list in that situation.
- Clarification has been provided as to the role of people with parental responsibility when the case involves a child.

6. Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment is not considered necessary in respect of the Code of Practice. They impose no direct costs and are part of operationalising

the 2013 Act. The costs associated with the Act were assessed at the time of its introduction and revised in June 2013 following Stage 2 scrutiny of the Bill.

Link to the Explanatory Memorandum and full Regulatory Impact Assessment for the 2013 Act:

http://www.assembly.wales/laid%20documents/pri-ld9121-em-r%20-%20revised%20explanatory%20memorandum%20human%20transplantation%20(wales)%20bill-25062013-247379/pri-ld9121-em-r-e-english.pdf