

EXPLANATORY MEMORANDUM

The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015

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 subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015. I am satisfied that the benefits outweigh any costs.

Mark Drakeford AM
Minister for Health and Social Services
9 September 2015

1. Description

The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 (“the Excluded Material Regulations”) describe organs and tissues which will be excluded for deemed consent. Express consent will be required for donation of any organs or tissues excluded by these Regulations.

The Excluded Material Regulations will come into force 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 Excluded Material Regulations are 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;
- **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 for approval at the same time. A separate Explanatory Memorandum has been prepared for each instrument.

3. Legislative background

The Human Transplantation (Wales) Act 2013 (“the 2013 Act”) 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.

4. Purpose and intended effect of the legislation

The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 are made under section 7(2) of the 2013 Act. The 2013 Act does not specify the types of organs and tissues which are to be donated, but instead refers to “relevant material” under the Act. Reproductive cells (gametes), embryos outside the body, hair and nail from the body of a living person are not considered to be “relevant material” under 2013 Act. However, all other material is included.

During scrutiny of the Human Transplantation (Wales) Bill, Ministers made a commitment to exclude certain organs and tissues – so-called novel forms of transplants – from deemed consent. Examples of such exclusions would be face or limb transplants. Ministers agreed that consent should only be able to be deemed for donation of routinely used organs i.e. those that a person might normally expect when they join the Organ Donor Register.

The Regulations therefore set out a clear list of those materials which will not fall within deemed consent. These materials will only be able to be donated when express consent is given.

5. Consultation

A consultation was held between 23 October 2014 and 15 January 2015 on the three sets of draft Regulations set out at section 2 above. In total, seventeen responses to the consultation were received. Four responses were received after the closing date, but were still considered. The latest response was received on 27 January 2015. Not all respondents commented on all of the Regulations and some made no specific comments on the Regulations themselves, preferring instead to make general comments about the new law.

Responses were received from a mixture of individuals, NHS organisations, medical organisations and non-medical organisations, such as charities. One respondent chose to remain anonymous.

The majority of those who responded felt the Excluded Relevant Material Regulations were clear and effective and that they were framed in the correct manner. People agreed that it was preferable to have a list of excluded materials (as appeared in the draft Regulations) as opposed to creating a list of organs for which consent could be deemed. Respondents felt that listing the materials in this way would reduce the possibility of unintended consequences.

Some minor alterations were made to the draft Regulations to reflect comments received during the consultation.

Brain and spinal tissue was added to the list of excluded materials. Nervous tissue was suggested as an exclusion but this was not taken forward because a small amount of nervous tissue is taken in all organ donations.

The eye was also included on the list of excluded materials in the consultation draft, however, this was changed following comments received, as the whole eye needs to be removed to facilitate sclera and cornea donation.

The list of excluded materials is now set out into **composite tissues**, meaning whole recognisable structures; and **sexual and reproductive tissues**. The tissues which make up the composite tissue are not excluded in their own right.

6. Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment is not considered necessary in respect of the Excluded Materials Regulations. 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](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)