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Llywodraeth Cymru
Welsh Government

Welsh Government
Consultation Document

Human Transplantation (Excluded Relevant Material) (Wales) (Amendment) Regulations

Consultation on draft regulations

Date of issue: 27 February 2020
Action required: Responses by 30 April 2020

Mae'r ddogfen yma hefyd ar gael yn Gymraeg.
This document is also available in Welsh.

Overview

A system of 'deemed consent' or 'opt out' for organ donation has been in place in Wales since 1st December 2015. In 2020, a similar system will be introduced in England.

The UK Government has recently consulted upon a set of regulations – the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2019 – which set out those materials which will be excluded from deemed consent, and for which express consent for transplantation will always be required. These regulations are the equivalent of the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015, which are already in force in Wales.

The Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 ('the 2015 regulations') now require amendment to achieve parity across the UK wide system of organ donation, and to take account of advancements in medical science.

This consultation asks for views on a set of amendment regulations which will add to the existing list of tissues which are excluded from deemed consent in Wales. The amendment regulations – the Human Transplantation (Excluded Relevant Material) (Wales) (Amendment) Regulations 2020 - are published in draft as part of this consultation.

How to respond

Please submit your comments **by 30 April 2020** in any of the following ways:

- Via the online form
- Via email or post using the contact details below

Further information and related documents

Large print, Braille and alternative language versions of this document are available on request.

Contact details

For further information:

Value Based Healthcare and Major Health
Conditions Branch
Population Healthcare Division
Health and Social Services Group
Welsh Government
Cathays Park
Cardiff
CF10 3NQ

Email: organ.donation@gov.wales

General Data Protection Regulation (GDPR)

The Welsh Government will be data controller for any personal data you provide as part of your response to the consultation. Welsh Ministers have statutory powers they will rely on to process this personal data which will enable them to make informed decisions about how they exercise their public functions. Any response you send us will be seen in full by Welsh Government staff dealing with the issues which this consultation is about or planning future consultations. Where the Welsh Government undertakes further analysis of consultation responses then this work may be commissioned to be carried out by an accredited third party (e.g. a research organisation or a consultancy company). Any such work will only be undertaken under contract. Welsh Government's standard terms and conditions for such contracts set out strict requirements for the processing and safekeeping of personal data.

In order to show that the consultation was carried out properly, the Welsh Government intends to publish a summary of the responses to this document. We may also publish responses in full. Normally, the name and address (or part of the address) of the person or organisation who sent the response are published with the response. If you do not want your name or address published, please tell us this in writing when you send your response. We will then redact them before publishing.

You should also be aware of our responsibilities under Freedom of Information legislation

If your details are published as part of the consultation response then these published reports will be retained indefinitely. Any of your data held otherwise by Welsh Government will be kept for no more than three years.

Your rights

Under the data protection legislation, you have the right:

- to be informed of the personal data held about you and to access it
- to require us to rectify inaccuracies in that data
- to (in certain circumstances) object to or restrict processing
- for (in certain circumstances) your data to be 'erased'
- to (in certain circumstances) data portability
- to lodge a complaint with the Information Commissioner's Office (ICO) who is our independent regulator for data protection.

For further details about the information the Welsh Government holds and its use, or if you want to exercise your rights under the GDPR, please see contact details below:

Data Protection Officer:
Welsh Government
Cathays Park
CARDIFF
CF10 3NQ

e-mail:

Data.ProtectionOfficer@gov.wales

The contact details for the Information Commissioner's Office are:

Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Tel: 01625 545 745 or
0303 123 1113

Website: <https://ico.org.uk/>

Human Transplantation (Excluded Relevant Material) (Wales) (Amendment) Regulations:

Consultation on draft regulations

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Foreword by the Minister for Health and Social Services

I am very pleased that Wales was the first country in the UK to introduce a system of deemed consent to organ donation as one way to address the shortage of organs for transplant. The Human Transplantation (Wales) Act 2013 came into force on 1st December 2015, and over the past few years we have seen Wales achieve the highest number of donors we have ever seen, as well as attaining the highest consent rate in the UK.

Since then, other parts of the UK have been watching to see the effect deemed consent would have. Having seen the success of the scheme here in Wales, it is good to see that England and Scotland are now following our lead by introducing similar systems. We have learned a lot along the way and have been pleased to share this with colleagues in other parts of the UK.

Introducing the new system elsewhere inevitably highlights new issues and means that we must make any necessary updates here in Wales, in order to ensure the system operates effectively across the UK. One such update is to the list of “excluded relevant materials” which we set out in regulations in 2015. The organs and tissues on that list are those which cannot be donated under deemed consent, in particular, novel forms of transplant and reproductive materials. The list now needs further updating to anticipate potential technological advances and to achieve parity across the UK wide system of organ donation.

I hope you will agree that the changes proposed to the 2015 regulations are sensible and proportionate, and I look forward to receiving your responses to the consultation.

Vaughan Gething AM

What this consultation is about

1. The Human Transplantation (Wales) Act 2013 ('the Act') came into force on 1st December 2015, introducing a system of deemed consent for organ donation in Wales. This means that where an adult in Wales has not opted out, it is lawful to deem their consent to organ donation. To support the implementation of the Act, three sets of regulations were made under powers afforded to Welsh Ministers within the Act, towards the end of 2015. This included the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 ('the 2015 regulations'), which can be found at the link below.

<http://www.legislation.gov.uk/wsi/2015/1775/made>

2. The 2015 regulations list the materials which are excluded from deemed consent and for which the express consent of the donor or their family will always be needed. The list includes so-called 'composite tissues' which includes face, limbs and other recognisable body parts, as well as reproductive tissues and sexual organs. During the passage of the Human Transplantation (Wales) Bill, Ministers agreed that not all organs and tissues should be subject to deemed consent, and that novel or contentious transplants should be excluded. These regulations fulfilled that commitment.
3. Deemed consent will come into force in England from spring 2020, and so the UK Government has consulted on an equivalent set of regulations to the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015. These regulations are called the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2019.
4. The England and Wales regulations have broadly the same effect, albeit there are some differences in the drafting style. Whilst the draft England regulations are similar to the 2015 regulations, there have been a number of additions to reflect the consultation responses and to future-proof the system in relation to new technologies.

<http://www.legislation.gov.uk/ukdsi/2020/9780111193372/contents>

5. The Welsh Government is of the view that amendments should be made to the 2015 Regulations, to add the additional materials which are listed within the England draft regulations. This will help achieve parity across the UK-wide system of organ donation and ensure that we keep up to date with advancements in medical science.
6. This consultation therefore sets out, and asks for views on, the changes we would like to make to the 2015 regulations.
7. No Impact Assessment has been produced for the draft regulations as they intend to maintain the current regime, where the express permission of the donor or their family will continue to be required for a novel or rare transplant to proceed. Therefore, no impact is foreseen in terms of adding to the list of materials.

8. It is important to note that the transplantation of most of the organs and tissues we are proposing to add to the list in the 2015 regulations is not currently possible and that the purpose of the amendments is to give clarity and certainty that if and when they do become possible, they will be outside the scope of deemed consent. In addition, these amendments do not alter the position that a person remains entitled to opt out of organ donation altogether, or to specify which organs they wish to donate on the Organ Donor Register - all of this remains unaffected by the proposed amendments to the 2015 regulations.

Changes proposed by the draft regulations

9. We are planning to make the following changes to the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 (the 2015 regulations). These changes are needed to ensure parity with the proposed regulations which will be in place in England to support the introduction of deemed consent there.

Additions to the list at regulation 2(2) of the 2015 regulations

10. We propose to add the following composite tissue to the list of excluded composite tissues at regulation 2(2) of the 2015 regulations:
 - Trachea
11. The trachea (windpipe) did not appear on the original list contained within the 2015 regulations, but we understand that there are several transplant procedures being undertaken in other countries which may be done in the UK at some point in the future. This includes trachea transplantation. As this would be regarded as a novel form of transplantation, we consider that it should be added to the list. However, a trachea would not be excluded if taken as part of a heart-lung transplant, and this is provided for in a new section within regulation 2 of the 2015 regulations. This is because we do not want to exclude materials which would normally be donated as part of more common and established transplants that are offered on the NHS.

Additions to the list at regulation 2(3) of the 2015 regulations

12. We want to add the following sexual and reproductive organs and tissues to the list of excluded relevant materials at regulation 2(3):
 - Cervix
 - Clitoris
 - Fallopian Tube
 - Labia
 - Vagina
 - Vulva
 - Prostate
 - Perineum
13. These tissues did not appear on the original list contained within the 2015 regulations. However, in light of responses to the consultation in England where we understand it was felt that further parts of the female and male reproductive systems should be added to the list, we would propose that they should now be included.

Addition of a new section within regulation 2 of the 2015 regulations

14. We propose to add a new section within regulation 2 to include the following types of cells utilised in Advanced Therapy Medicinal Products (ATMPs):

- Limbal stem cells
- Liver cells
- Lung epithelial cells
- Pancreatic cells
- Renal epithelia cells

15. ATMPs are medicines that contain tissues, cells or genes after manipulation in a laboratory and are used for the treatment of injuries and diseases. There is now at least one that contains transplant material from deceased donors.

Retention of ‘eye’ within regulation 2(4) of the 2015 regulations

16. We do not propose to remove ‘eye’ from within regulation 2(4), despite the fact that it is not listed within the equivalent provision in England’s draft regulations. Regulation 2(4) contains a list of materials that are only excluded from deemed consent if they are used in connection with the transplantation of composite tissues listed in regulation 2(2). In other words, they are not excluded from deemed consent in their own right. For example, skin is only excluded if it is being transplanted as part of a leg transplant. We understand that clinical advice provided to the UK Government indicated that eyes would not be retrieved as part of a face transplant, should face transplants become possible in the UK in the future. However, we propose to keep this material in place so that should it ever become technically possible to transplant a whole eye as part of a face transplant, then express consent would always be needed to do so.

17. This does not affect the ability of people to donate corneas under deemed consent, which remains in place. There is no divergence of policy between Wales and England in this respect. The regulations in Wales explicitly specify the eye as excluded from deemed consent in connection with the transplant of a composite tissue (which could only be the face), whereas England do not specify it on the basis that eyes would not form part of a face transplant.

**Consultation
Response Form**

Your name:

Organisation (if applicable):

Email / telephone number:

Your address:

Question 1: Do you believe the changes we are planning to make to the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 are clear, achieve parity across the UK-wide system of organ donation and ensure we keep up to date with advancements in medical science?

Yes

No

If no, please state why

Question 2: Do you agree with the proposed new additions to the 2015 regulations (i.e. trachea to regulation 2(2); further sexual and reproductive tissues to regulation 2(3) and a new paragraph in regulation 2 about cells used in Advanced Therapy Medicinal Products?

Yes

No

If no, please state why

Question 3: Do you agree that 'eye' should remain in regulation 2(4), so that were the eye(s) ever able to be transplanted as part of a face transplant, express consent for the transplant of the eye(s) would always be required?

Yes

No

If no, please state why

Question 4: We would like to know your views on the effects that the changes we want to make to the 2015 regulations would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favourably than English.

What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

Question 5: Please also explain how you believe the proposed changes could be formulated or changed so as to have positive effects or increased positive effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language, and no adverse effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language.

Question 6: We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:

Please enter here:

Responses to consultations are likely to be made public, on the internet or in a report. If you would prefer your response to remain anonymous, please tick here: