

Human Tissue (Authorisation) (Excepted Body Parts) (Scotland) Regulations 2020

Consultation

February 2020



Scottish Government
Riaghaltas na h-Alba
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Important note when reviewing this consultation document, its content and questions.

The Scottish Government is seeking views, in accordance with the Human Tissue (Authorisation) (Scotland) Act 2019, on which parts of the body should be listed in regulations as exempt from deemed authorisation and in what circumstances.

Views are primarily sought from the clinical community who have experience of the deceased donation and transplantation pathway, and their representative organisations and bodies.

This consultation paper outlines the context in which donation and transplantation takes place. Please review the paper before answering the questions.

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Introduction

About this consultation

1. A deemed authorisation system of deceased organ and tissue donation for transplantation will come into effect in Scotland in autumn 2020¹. This is commonly referred to as an 'opt out' system.
2. It is proposed that deemed authorisation will only apply to the commonly transplanted organs and tissue and will not apply to novel or rare transplants. Applying deemed authorisation to only the more commonly donated types of organ and tissue reflects a measured approach in introducing deemed authorisation, and should avoid the unintended consequence of people deciding to opt out purely due to concern about donating a particular, rarely donated body part even though such donation would be extremely unlikely.
3. This consultation is seeking views on proposed draft regulations which will make clear which parts of the body deemed authorisation will not apply to. In practice donation and transplantation of these parts of the body is rare or doesn't happen in the UK however it is important to set the exclusions out in regulations in order to provide certainty about what is included in deemed authorisation.
4. The Scottish Government would welcome views on the proposed list of parts to be excluded from deemed authorisation and in particular on whether the proposed list would mean that deemed authorisation will include all and only those parts of the body which are currently commonly transplanted.

Practical context

5. The circumstances in which a person can become an organ donor are limited; organ donation usually only happens where the person has died in an intensive care unit in hospital. Only around 1% of people die in these circumstances. Tissue-only donation is slightly different as tissues can be donated up to 24 or 48 hours after death and currently tissue-only donation happens from a variety of hospital settings.
6. Currently, if someone has opted in to donation on the NHS Organ Donor Register (ODR), they can specify which of the commonly donated organs and tissue they want to donate. For example, it is possible for a person to say they want to donate certain organs and tissue but not their corneas. Under the opt-out system, people will still be able to use the ODR in the same way to specify which organs or tissue they wish to donate. In cases where organ or tissue donation is a possibility, specialist staff will discuss donation with the family, including which organs/tissues it is possible to donate in the specific circumstances.
7. Only certain organs and tissue are commonly donated for transplantation from deceased donors in Scotland or the rest of the UK. For organs these include the kidneys, liver, pancreas, heart, lungs, small bowel and stomach and for tissue these include heart tissue, tendons, skin, bone, blood vessels and corneas. Transplantation of these common types of organs and tissue is well established in the UK and is carried out frequently with a high degree of success.
8. More novel or rare transplants, for example involving limbs, are carried out very infrequently in the UK because of the much lower level of need or demand.

¹ <https://news.gov.scot/news/autumn-2020-for-organ-donation-opt-out-system>

9. If a potential donor could be a suitable match for a novel or rare organ or tissue for a patient waiting for such a transplant, it would only take place when there is appropriate authorisation in place and with the support of the donor's family.
10. Including the parts of the body which may be the subject of more novel or rare transplants as part of the deemed authorisation system would be unlikely to increase their availability for transplantation.

Legislative context

11. On 11 June 2019 the Scottish Parliament passed the Human Tissue (Scotland) Act 2019 ('Human Tissue (Authorisation) (Scotland) Act 2019'). This legislation amends the Human Tissue (Scotland) Act 2006 ('the 2006 Act') and provides for a deemed authorisation system of deceased organ and tissue donation for transplantation to take effect in Scotland. This is commonly referred to as an 'opt out' system of organ and tissue donation, replacing the 'opt in' framework currently in place. The Scottish Government has announced that the new deemed authorisation system will come into force in autumn 2020.
12. The legislation provides that when a person has not recorded an opt-in or opt-out decision, they may be deemed to have authorised donation of their organs and tissue after their death for transplantation. This is subject to a number of safeguards set out in the legislation which seek to ensure that donation doesn't proceed where it would be against the wishes of the potential donor. Transplantation is the only purpose for which authorisation can be deemed – authorisation cannot be deemed for research or any other purpose.
13. In order to provide certainty about the scope of deemed authorisation, regulations will set out which parts of the body deemed authorisation will not apply to, referred to in the 2019 Act as 'excepted body parts'.
14. If an adult is deemed to have authorised donation for transplantation, only parts of the body which are not listed as excepted body parts will be able to be donated under deemed authorisation. In such cases, authorisation for donation of the excepted body parts for transplantation may be given by the donor's family, provided they have no knowledge that the adult would have been unwilling to donate these parts. However based on current practice, it would be rare that a family would be approached about the possibility of donation of excepted body parts.
15. Section 6D(5) of the Human Tissue (Scotland) Act 2006 inserted by section 7 of the 2019 Act provides for Scottish Ministers to make regulations to specify parts of the body which are excluded from deemed authorisation - The Human Tissue (Excepted Body Parts)(Scotland) Regulations 2020. The proposed content of these regulations, in the form of lists of parts of the body, is set out from page 7.
16. Listing these parts in secondary legislation will mean that the list can be updated if required. If a novel transplant became standard practice and there was clinical demand for transplants of that body part, then, following clinical advice and evidence the Scottish Government would consider removing it from the list of body parts which are excluded from deemed authorisation. However it is not expected that this will happen in the near future. Before proposing any such changes, the Scottish Government would consult with NHS Blood and Transplant (NHSBT), the Scottish National Blood Transfusion Service (SNBTS), clinicians, and any other relevant clinical stakeholders, before carrying out wider

consultation. The Scottish Government will discuss with the Scottish Donation and Transplant Group arrangements which might be put in place for it and other clinical stakeholders to consider the clinical rationale for any potential changes to the Regulations.

Background

Novel and rare types of transplants

17. Medical science can advance rapidly, making new procedures and types of transplants possible. However, it can take many years for a new transplantation procedure to become standard practice. This is because of the need for careful evaluation at each stage of its development to ensure that it is safe, effective, ethical for patients, and meets the needs of the population.
18. Limb donation is a rare form of donation. Limb transplants are already offered in Leeds General Infirmary for patients across the UK. There is a very small number of patients who need a limb transplant - there have only been 6 limb transplants in the UK since 2012.
19. There is a small number of novel transplants from deceased donors being developed in the UK such as face transplants. In addition, there are several transplant procedures currently undertaken in other countries, which may be taken forward in the UK at some point in the future, for example penis transplantation.

2016 Consultation on increasing the number of successful donations

20. The Scottish Government consulted on ways to increase donation, including through the introduction of an opt out system of deceased donation, from late 2016 into early 2017. The consultation proposed that deemed authorisation should only apply to the commonly transplanted organs and tissue² and sought views on this.
21. The majority of individual respondents (83%) expressed a preference that deemed authorisation should apply to all parts of the body for transplantation, without exception. Conversely, organisational respondents (such as NHS boards, local authorities, professional bodies etc.) were more evenly split, with 46% of respondents in favour of deemed authorisation applying to all parts of the body, and 54% in favour of deemed authorisation applying only to the more commonly transplanted organs and tissue.³
22. Including all parts of the body in deemed authorisation is unlikely to increase the number of successful novel or rare transplantations as donation and transplantation of such body parts is rare because of the low level of need, rather than because of an absence of authorisation. Excluding certain parts of the body from deemed authorisation is also consistent with the approach in other parts of the UK and given the UK-wide collaboration on donation and transplantation it is beneficial to take a similar approach.
23. Applying deemed authorisation to only the more commonly transplanted types of organ and tissue reflects a measured approach and aims to avoid the unintended consequence of people deciding to opt out of donation due to concern about donating a particular, rarely donated, body part even though such donation would be extremely unlikely.

² Page 18: https://consult.gov.scot/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf

³ Page 43-44: <https://consult.gov.scot/health-protection/organ-and-tissue-donation-and-transplantation/results/organ-and-tissue-donation-and-transplantation-analysis-of-responses.pdf>

24. Our proposed approach reflects the position set out in the 2016 consultation that deemed authorisation will not apply to novel or rare transplants.

UK Context

25. Solid organ and eye donation and transplantation is coordinated across all UK nations by NHS Blood and Transplant (NHSBT), a special health authority for England and Wales. This means that an organ donated in Scotland could be transplanted into a recipient in another part of the UK. Similarly an organ donated in another part of the UK could be transplanted into a recipient in Scotland.

26. The Scottish National Blood Transfusion Service (SNBTS) coordinates deceased donation and also provision of other tissues for transplantation across NHS Scotland.

27. Similar regulations to those proposed in Scotland are in effect in Wales⁴ and have been consulted upon in England⁵, and they reflect the respective legislation in those jurisdictions. Similarly the Scottish regulations reflect the legislative framework in place in Scotland and so do not replicate the English and Welsh regulations. As far as is possible the effect is intended to be broadly the same, and differences in the regulations, either in drafting or effect will not affect cross-border transfer.

Intention of proposed regulations

28. The purpose of the excepted body parts regulations is to make clear which parts of the body deemed authorisation does not apply to. This applies the same principle adopted in Wales and England, where it was considered preferable to list parts of the body to which deemed authorisation doesn't apply, as opposed to creating a list for which authorisation could be deemed. Our aim is to ensure that organs and tissue which are commonly transplanted are able to be donated with deemed authorisation. The regulations don't affect which organs/tissue may be donated under express authorisation, although in practice it will be rare for the 'excepted body parts' as listed in the regulations to be donated for transplantation under express authorisation, due to the low level of clinical need.

Definitions and terminology

29. The terminology used in the regulations reflects the legal framework in Scotland. Definitions of terms used in the regulations are provided below to assist in the understanding of this consultation:

- **Body parts:** The term used in the 2006 Act, as amended by the 2019 Act to encompass parts of the body which may be authorised to be removed and used for transplantation. This term includes organs and tissue.
- **Excepted body parts:** The term used in the 2019 Act to encompass parts of the body, to be listed in regulations, that deemed authorisation will not apply to.

⁴ <http://www.legislation.gov.uk/wsi/2015/1775/contents/made>

⁵ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/798467/Organs_and_tissues_to_be_excluded_from_the_new_system_of_organ_and_tissue_donation_in_England_-_consultation_document.pdf

The excepted body parts

30. The proposed regulations list body parts in three different groups, depending on how they are treated in relation to deemed authorisation.

Group 1

31. It is proposed that the below list of body parts (group 1) are those which are excluded from deemed authorisation in all circumstances. These body parts can only be donated with explicit authorisation:

- **Group 1 - body parts excluded from deemed authorisation in all circumstances**

- brain
- cervix
- clitoris
- fallopian tube
- labia
- ovary
- penis
- perineum
- placenta
- prostate
- spinal cord
- testicle
- trachea
- umbilical cord
- uterus
- vagina
- vulva

Group 2

32. In order to ensure that current tissue donation practice is not inadvertently adversely impacted by the regulations, they set out that tissue from certain excepted body parts (those listed in group 2) may be donated under deemed authorisation. For example an area of skin taken from the leg to be used in treatment for burns victims could be donated with deemed authorisation, but the leg in its entirety couldn't be removed with deemed authorisation. Without this measure, tissue donation in Scotland could be significantly adversely impacted which would limit the chances of those waiting for tissue transplants to receive the transplant they need.

33. Reflecting this, it is proposed that body parts listed below (group 2) would require explicit authorisation when they are being donated in their entirety. However from this list only those parts making an arm transplant (upper arm; fore arm; hand; finger) are currently transplanted from deceased donors in the UK. Where only tissue (listed in group 3) which forms part of the body part is being removed, it would be able to be removed under deemed authorisation:

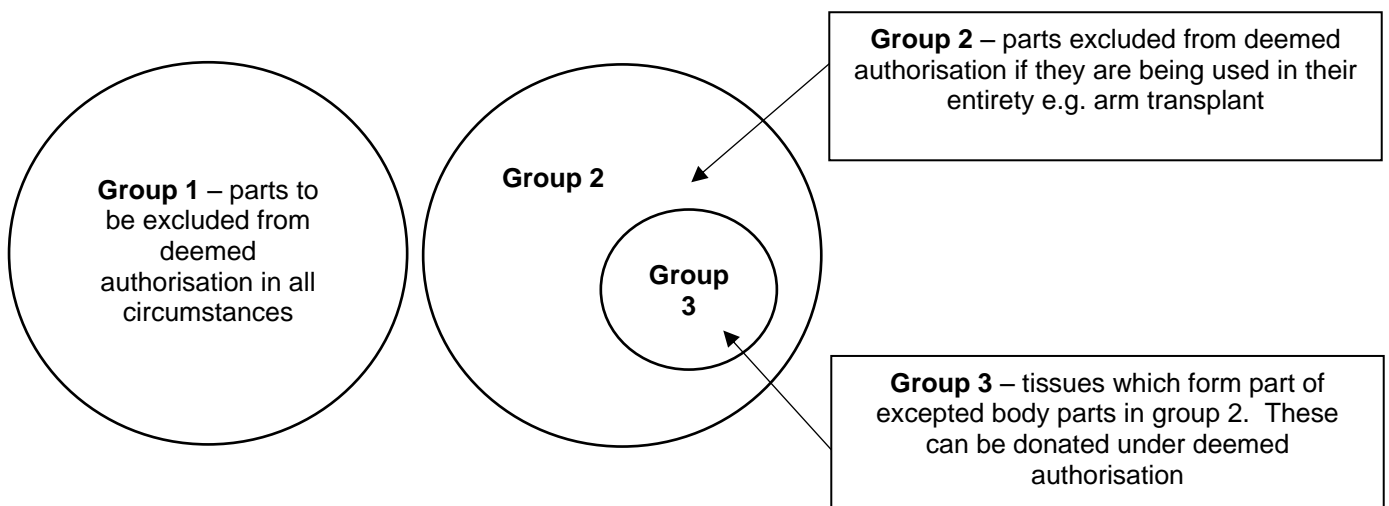
- **Group 2 - body parts excluded from deemed authorisation if being donated in their entirety**
 - face (meaning the front part of the head, from the forehead to the chin and containing the nose and mouth but excluding the eyes)
 - finger
 - foot
 - forearm
 - hand
 - lower leg
 - thigh
 - toe
 - upper arm

Group 3

34. It is proposed that the following tissue which forms part of an excepted body part included in group 2 could be donated with deemed authorisation:

- **Group 3 – tissue which can be donated from a body part in group 2 with deemed authorisation**
 - blood vessel (meaning arteries, arterioles, capillaries, venules and veins)
 - bone
 - muscle
 - nervous tissue
 - skin
 - tendon

Figure 1 – How the excepted body parts regulations function

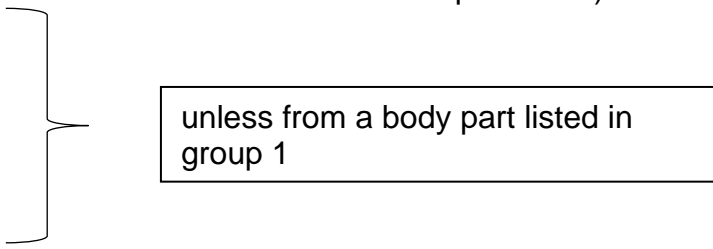


35. The procurement, storage and use of gametes or 'reproductive cells' is dealt with under the Human Fertilisation and Embryology Act 2008 ("the 2008 Act") and requires a Human Fertilisation and Embryology Authority licence. It is dealt with separately from the 2006 Act and the 2019 Act and the introduction of these proposed regulations won't change the requirements set out in the 2008 Act.

Parts of the body which would be included in deemed authorisation

36. The effect of the proposed regulations would be that all body parts which are not listed in either group 1 or 2, as well as the tissue listed in group 3, would be able to be donated under deemed authorisation. This means that **deemed authorisation for transplantation will apply to all of the following parts of the body:**

- heart
- lungs
- kidneys
- liver (including for liver cell transplantation)
- pancreas (including for islet transplantation)
- intestinal organs
- heart tissue (valves, conduits and patches)
- eyes (including for both cornea and sclera transplantation)
- nervous tissue
- blood vessels
- bone
- muscle
- tendon
- skin



unless from a body part listed in group 1

Consultation questions

Question 1. Group 1: The parts of the body to be excluded from deemed authorisation in all circumstances:

- a) Are there any parts of the body in group 1 that should not be listed? Please explain below.

- b) If there is anything that is missing from group 1, please comment here giving reasons why.

Question 2. Group 2: The parts of the body to be excluded from deemed authorisation, if they are to be used in their entirety:

- a) Are there any parts of the body in group 2 that should not be listed? Please explain below.

- b) If there is anything that is missing from group 2, please comment here giving reasons why.

Question 3. Group 3: Tissues which form part of body parts listed in group 2 to be included in deemed authorisation:

- a) Are there any tissues that should not be listed? Please explain below.

- b) If there is anything that is missing from group 3, please comment here giving reasons why.

Question 4. Do you have any other comments on this consultation?

How to respond

Responding to this Consultation

1. We are inviting responses to this consultation by **27 March 2020**.
2. Please respond to this consultation using the Scottish Government's consultation hub, Citizen Space (<http://consult.gov.scot>). Access and respond to this consultation online at <https://consult.gov.scot/population-health/human-tissue-regulations-2019/>. You can save and return to your responses while the consultation is still open. Please ensure that consultation responses are submitted before the closing date of **27 March 2020**.
3. If you are unable to respond using our consultation hub, please complete the Respondent Information Form (Annex A) to:

Opt Out Donation Legislation Team
Scottish Government
3 East
St Andrews House
Regent Road
Edinburgh, EH1 3DG

Handling your response

4. If you respond using the consultation hub, you will be directed to the About You page before submitting your response. Please indicate how you wish your response to be handled and, in particular, whether you are content for your response to be published. If you ask for your response not to be published, we will regard it as confidential, and we will treat it accordingly.
5. All respondents should be aware that the Scottish Government is subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.
6. If you are unable to respond via Citizen Space, please complete and return the Respondent Information Form included in this document.
7. To find out how we handle your personal data, please see our privacy policy: <https://beta.gov.scot/privacy/>

Next steps in the process

8. Where respondents have given permission for their response to be made public, and after we have checked that they contain no potentially defamatory material, responses will be made available to the public at <http://consult.gov.scot>. If you use the consultation hub to respond, you will receive a copy of your response via email.
9. Following the closing date, all responses will be analysed and considered along with any other available evidence to help us. Responses will be published where we have been given permission to do so. An analysis report will also be made available.

Comments and complaints

10. If you have any comments about how this consultation exercise has been conducted, please send them to the contact address above or at ODlegislation@gov.scot.

Scottish Government consultation process

11. Consultation is an essential part of the policymaking process. It gives us the opportunity to consider your opinion and expertise on a proposed area of work.
12. You can find all our consultations online: <http://consult.gov.scot>. Each consultation details the issues under consideration, as well as a way for you to give us your views, either online, by email or by post.
13. Responses will be analysed and used as part of the decision making process, along with a range of other available information and evidence. We will publish a report of this analysis for every consultation. Depending on the nature of the consultation exercise the responses received may:
 - indicate the need for policy development or review
 - inform the development of a particular policy
 - help decisions to be made between alternative policy proposals
 - be used to finalise legislation before it is implemented
14. While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body.

Annex A: Respondent Information Form

Consultation on the Human Tissue (Excepted Body Parts) (Scotland) Regulations 2020

Please Note this form **must** be completed and returned with your response.

To find out how we handle your personal data, please see our privacy policy:
<https://beta.gov.scot/privacy/>

Are you responding as an individual or an organisation?

- Individual
 Organisation

Full name or organisation's name

Phone number

Address

Postcode

Email

The Scottish Government would like your permission to publish your consultation response. Please indicate your publishing preference:

- Publish response with name
 Publish response only (without name)
 Do not publish response

Information for organisations:

The option 'Publish response only (without name)' is available for individual respondents only. If this option is selected, the organisation name will still be published.

If you choose the option 'Do not publish response', your organisation name may still be listed as having responded to the consultation in, for example, the analysis report.

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

Yes

No

Question 1. Group 1: The parts of the body to be excluded from deemed authorisation in all circumstances:

a) Are there any parts of the body in group 1 that should not be listed? Please explain below.

b) If there is anything that is missing from group 1, please comment here giving reasons why.

Question 2. Group 2: The parts of the body to be excluded from deemed authorisation, if they are to be used in their entirety:

a) Are there any parts of the body in group 2 that should not be listed? Please explain below.

b) If there is anything that is missing from group 2, please comment here giving reasons why.

Question 3. Group 3: Tissues which form part of body parts listed in group 2 to be included in deemed authorisation:

a) Are there any tissues that should not be listed? Please explain below.

b) If there is anything that is missing from group 3, please comment here giving reasons why.

Question 4. Do you have any other comments on this consultation?



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Any enquiries regarding this publication should be sent to us at

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