

ORGAN DONATION (DEEMED CONSENT) BILL

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Organ Donation (Deemed Consent) Bill as brought from the House of Commons on 29 October 2018 (HL Bill 141).

- These Explanatory Notes have been produced by the Department of Health and Social Care, with the consent of Lord Hunt of Kings Heath, the Member in charge of the Bill, in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Bill. They are not, and are not intended to be, a comprehensive description of the Bill.

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Overview of the Bill

- 1 The current law on consent for the use of bodies and relevant materials is set out in the Human Tissue Act 2004 (“the 2004 Act”). The 2004 Act, among other things, makes provision with respect to activities involving human tissue, such as organ transplantation, and authorises the removal, storage and use of organs and tissues for the purpose of transplantation if there is “appropriate consent”. The meaning of appropriate consent differs depending on whether the relevant material is obtained from an adult or child, but, under the 2004 Act as it currently stands, the overarching principle is that consent must be given expressly and cannot be deemed to have been given in the absence of an objection.
- 2 The Bill amends the 2004 Act to introduce provisions that would allow for consent to organ and tissue donation in England to be deemed to have been given by a potential adult organ donor before their death unless they had expressly stated that they did not wish to be an organ donor or an exception applies. This is often referred to as an “opt-out” system of consent as people may “opt-out” of becoming an organ donor if they do not consent. The Bill does not propose any changes to the rules on consent to organ donation in respect of children under 18 or people who have expressly made a decision on consent before their death (either by recording their decision to give or refuse consent or appointing someone to make that decision on their behalf). This Bill also does not propose changes to consent concerning living donations. Further, the Bill sets out that deemed consent will not apply where a person in a qualifying relationship to the deceased (partners, certain family members or a friend of long standing) provides information that would lead a reasonable person to conclude that the deceased potential organ donor would not have consented to be an organ donor. The Bill also provides exceptions applicable to the following groups of adults, in respect of whom the deemed consent provisions will not apply:
 - people who are short-term visitors or temporarily resident in England for less than 12 months immediately before dying. Examples include overseas workers, students, overseas Armed Forces personnel; and
 - people who lack the capability to fully understand the consequences of deemed consent for a significant period before dying.
- 3 Deemed consent will not apply to all organs and tissues. Organs and tissues that are to be excluded from deemed consent will be set out in regulations made by the Secretary of State. These will cover transplants that are currently rare and many may not regard as normal to donate.

Policy background

- 4 The donation of organs and tissues after death helps to save thousands of lives in England each year. Just one donor could transform the lives of up to nine other people. In 2017, national figures confirmed that over 50,000 people are known to be alive thanks to organ donation and transplantation.¹
- 5 There is widespread public support for organ donation, with around 80% of people saying that they support organ donation ‘in principle’, and would be willing to donate their organs and tissue after they have died. Over the last 10 years, the number of organ donors has increased by 75% and deceased transplants have increased by 56%.² There are almost 25 million people on the NHS Organ Donor Register.

¹ <https://www.organdonation.nhs.uk/news-and-campaigns/news/more-than-50-000-people-now-alive-thanks-to-organ-donation-and-transplant/>

² <https://www.nhsbt.nhs.uk/>

- 6 Despite this, there is a shortage of donors in England, with around 5,100 people waiting for a transplant. Over half a million people die each year in the UK, but only around 5,000 people die in circumstances or from conditions that mean that their organs could be considered for transplantation.
- 7 Since the introduction of an opt-out system in Wales, consent rates in Wales have increased from 58% in 2015 to 72% in 2017.³ However, UK consent rates overall are below the ambitious targets set out in the current UK strategy. Because of this shortage, three people die each day due to a lack of suitable organs. The situation is worse for people from black and Asian backgrounds who, due to genetic differences, are more likely to suffer from an illness that may lead to them needing a transplant. Due to the shortage of matched donors (donors with the same blood and tissue type, usually from the same ethnic group), people from these communities will wait six months longer on average if they need an organ transplant.⁴
- 8 Under the current rules in England, a person is considered a possible organ donor following their death only if they actively took steps to consent in their lifetime. In practice, this is usually a question of whether they have signed the NHS Organ Donor Register and/or discussed their views with their family. Families can also give consent.
- 9 The purpose of the Bill is to change the way in which consent is to be given for organ and tissue donation in England, for the purposes of transplantation. The Bill provides that, in the absence of a deceased adult having made express provision in relation to consent before their death or having appointed someone to make a decision on consent for them, the default position in most cases will be that consent will be deemed to have been given. This means that, after death, a person will be considered to have consented to organ donation in their lifetime unless they made specific provision to the contrary in their lifetime, they appointed someone to make the decision on their behalf, or there is evidence that would lead a reasonable person to conclude that they would not have consented or an exception applies. It should be noted that these changes on the rules of consent would not apply in respect of all people and deemed consent does not apply to under 18s, as well as certain excepted adults - people who lacked capacity for a significant period before their death such that they could not understand that consent could be deemed in the absence of express action being taken, and people who had not been ordinarily resident in England for at least 12 months immediately before their death.
- 10 The policy underlying many of the provisions in this Bill was consulted on in the Government consultation [Introducing 'opt-out' consent for organ and tissue donation in England](#), which was launched in December 2017. The consultation sought views on a number of issues regarding the implementation of the new system of consent. The Government received more than 17,000 responses from individuals and organisations.
- 11 The Government's response to the consultation, [New approach to organ and tissue donation in England](#), was published on 5 August 2018. The Government set out its proposals for implementation. This includes changes to the Organ Donor Register to make it easier to record a decision, a 12-month transition period between the legislation and the changes coming into effect, to allow time for a public awareness campaign and new measures to accommodate concerns from faith groups.

Clause 1: “Appropriate consent” to adult transplantation activities: England

- 12 This provision amends the 2004 Act to set out when deemed consent amounts to appropriate consent for transplantation purposes. The policy background to this provision is to amend the law

³ <https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/>

⁴ <https://www.gov.uk/government/publications/race-disparity-audit>

regarding when consent is considered to have been given to better reflect the views of the 80% of the population that support organ donation in principle by shifting the default position in relation to consent away from an option to opt-in to an option to opt-out. There are, of course, people who actively made a decision before they died as to whether they do or do not consent to organ donation, or who opted to appoint someone to make that decision on their behalf. In these cases, as in the case of children and living donors, there is no change to the rules. The provision also provides for cases where certain people close to the deceased believe that they would not have consented to being an organ donor, and allows for the presumption of consent to be overturned.

- 13 The Government has amended the Bill to exclude novel transplants from deemed consent. This is to ensure that the new system of consent is in line with the common understanding of organ and tissue donation. The list of novel transplants will be detailed in regulations made by the Secretary of State following consultation. The regulations will be laid under an affirmative procedure (see Clause 2(5) and (6)).
- 14 Finally, there are exceptions to ensure that certain vulnerable groups and those that are not permanently resident in England are protected by a move to an opt-out consent system. This applies in respect of people who lacked capacity to understand deemed consent for a significant period before their death, and to visitors and short-term residents in England.

Clause 2: Consequential amendments

- 15 The purpose of these provisions is to ensure that any organs and tissues removed in England for transplantation purposes can be stored and used wherever needed across the UK, even where there was deemed rather than express consent to the removal of the organ. While the current legislative frameworks in respect of Wales and Scotland already allow for this to happen, without these amendments, only organs and tissue removed in England with express consent from the deceased, their representative or a family member or friend could be stored or used in Northern Ireland for transplantation purposes.
- 16 This clause also places a duty on the Human Tissue Authority to issue Codes of Practice to provide practical guidance about how deemed consent will work in practice, including the information a person in a qualifying relationship (partners, certain family members or a friend of long standing) would need to provide as evidence that the deceased person would not have agreed to their organs being donated.
- 17 This clause amends the 2004 Act to set out that the delegated power under Clause 1(5) for the Secretary of State to make regulations to specify relevant material to which deemed consent will not apply, is subject to the affirmative resolution procedure. It also sets out with whom the Secretary of State must consult on such regulations.

Clause 3: Extent, commencement and short title

- 18 This Bill extends to England and Wales and Northern Ireland. However, as is clear from the text of the amendments to section 3 of the 2004 Act in Clause 1, the deemed consent provisions only have practical application in respect of activities carried out in England. Clause 2(2) and (3) will apply in Northern Ireland, so the consent of the Northern Ireland Assembly will be sought, once it has been restored.
- 19 Apart from Clause 3, which comes into force on the day that the Act is passed, the provisions in this Bill will come into force on the day or days that the Secretary of State appoints through regulations made by statutory instrument.

Legal background

- 20 The 2004 Act, amongst other things, makes provision with respect to activities involving human tissue. Section 1(1) of the 2004 Act (authorisation of activities for scheduled purposes) sets out that certain activities are lawful if done with appropriate consent. Those activities include:
- storing the body of a person who has died for use for certain purposes specified in Schedule 1 to the 2004 Act (including transplantation – paragraph 7 of Schedule 1);
 - the use of the body of a person who has died for such a purpose;
 - the removal of “relevant material” from the body of a person who has died for such a purpose;
 - the storage of relevant material that has come from a human body for such a purpose; and
 - the use of relevant material that has come from a human body for such a purpose.
- 21 “Relevant material” is defined in section 53 of the 2004 Act. It is any material that consists of, or includes, human cells other than gametes, embryos outside the human body, and hair and nail from the body of a living person. Section 54(7) clarifies that material created outside the human body is not relevant material for the purposes of the 2004 Act.
- 22 Accordingly, under the 2004 Act it is lawful to remove, store and use organs and human tissue from a deceased person for the purposes of transplantation provided that appropriate consent is obtained. Section 2 of the 2004 Act sets out the meaning of appropriate consent for the purposes of section 1 in respect of children (a person under 18 (section 54(1))). The Bill will not make any amendment to this provision and the existing rules on when appropriate consent is given in respect of a child will continue to apply.
- 23 The meaning of “appropriate consent” for the purposes of section 1 in respect of an adult is set out in section 3 of the 2004 Act (“appropriate consent”: adults). The Bill does propose amendments to this section. Further information on the operation of those amendments is set out in the commentary on Clause 1 of the Bill in these Explanatory Notes. Under the 2004 Act as it currently stands, if the adult made no decision before death to either expressly give or refuse consent, a person that they nominated in accordance with section 4 of the 2004 Act may give or refuse consent. Failing that, someone in a “qualifying relationship” (as listed in section 54(9) and dealt with further at section 27(4)) may give consent. Failing that, there is no consent.

Territorial extent and application

- 24 This Bill extends to England and Wales and Northern Ireland, however, as is clear from the text of the amendments to section 3 of the 2004 Act in Clause 1, the deemed consent provisions only apply in respect of activities carried out in England. Clause 2(2) and (3) will apply in Northern Ireland so the consent of the Northern Ireland Assembly will be sought, once it has been restored.

Commentary on provisions of Bill

Clause 1: “Appropriate consent” to adult transplantation activities: England

- 25 Under section 1(1) of the 2004 Act, the removal, storage and use of organs and tissue from a deceased person is lawful if there is appropriate consent. Clause 1 sets out amendments to section 3 of the 2004 Act (“appropriate consent”: adults), which defines “appropriate consent” in respect of adults for the purposes of section 1.

- 26 Clause 1 inserts a new paragraph (ba) into section 3(6) of the 2004 Act. This new provision introduces deemed consent, in the absence of express consent. The amendments to section 3 of the 2004 Act in Clause 1 set out that with respect to specific listed transplantation activities carried out in England, in the absence of an express decision on consent either by the person before their death or by a person appointed to make that decision for them, deemed consent will apply unless –
- a person in a qualifying relationship to the deceased (as listed in section 54(9)) provides information that would lead a reasonable person to conclude that the deceased would not have consented (new subsection (6B) under subsection (4));
 - the deceased person had not been ordinarily resident in England for a period of at least 12 months immediately before they died (an “excepted” person under subsection (5)); or
 - the deceased person had, for a significant period before their death, lacked capacity to understand that deemed consent would apply (an “excepted” person under subsection (5)).
- 27 This clause also introduces a new term to the 2004 Act, “permitted material”. The Bill proposes that deemed consent will only apply in respect of “permitted material”. The Bill defines “permitted material” as relevant material other than relevant material of a type specified in regulations made by the Secretary of State. Relevant material that is to be excluded from deemed consent will be specified in regulations made by the Secretary of State. These regulations will be subject to an affirmative resolution procedure that applies to statutory instruments (as set out in Clause 2(5) and (6)).

Clause 2: Consequential amendments

- 28 Clause 2 makes further amendments to the 2004 Act as a consequence of the amendments made by clause 1 to section 3 of the 2004 Act. Clause 2 inserts in the 2004 Act a new subsection into section 1 after subsection (9B), and amends subsection (10)(c) to allow for the storage and use in Northern Ireland of relevant material removed from a human body in England for transplantation purposes.
- 29 This clause also inserts two new subsections in section 27 of the 2004 Act (provision with respect to consent). These new provisions place a duty on the Human Tissues Authority (HTA) to give practical guidance on how deemed consent will work in practice, including guidance about the provision of information by a family member or friend of the deceased to override the presumption of consent.
- 30 This clause amends section 52 of the 2004 Act to set out that the delegated power in Clause 1 for the Secretary of State to make regulations to specify relevant material to which deemed consent will not apply, is subject to the affirmative resolution procedure. It also sets out with whom the Secretary of State shall consult with on such regulations (subsections (5) to (7)).

Clause 3: Extent, commencement and short title

- 31 Clause 3 provides that the Bill extends to England, Wales and Northern Ireland, although Clause 1, the deemed consent provisions, only apply in respect of activities carried out in England. It also sets out that apart from Clause 3 which comes into force on the day that the Bill is passed, the rest of the provisions, Clauses 1 and 2 will come into force on a date, or dates, appointed in a statutory instrument by the Secretary of State. The clause also sets out the short title for the Bill on receiving Royal Assent as the Organ Donation (Deemed Consent) Act 2018.

Financial implications of the Bill

- 32 A full impact assessment was published alongside the Government's consultation on 12 December 2017, and an updated revision was published alongside the Government's response to the consultation on 5 August 2018.
- 33 A total estimate of £23.8m over the four-year transition period (from now until 2022) has been apportioned to the costs of the communications campaign and to build capability to absorb the increase in opt-out registrations on the Organ Donor Register.
- 34 A further costs of £44,210 per additional donor is expected to be incurred by NHS Blood and Transplant to cover operational costs (i.e. co-ordination team, training of specialist nurses etc.) to facilitate organ retrieval.
- 35 The total cost is dependent on the scale of the increase in the number of donations, which is uncertain at this stage.

Parliamentary approval for financial costs or for charges imposed

- 36 A Money resolution for the Bill was passed on 11 September 2018. A Money resolution is required where a bill authorises new charges on the public revenue – broadly speaking, new public expenditure. The provisions in the Bill may lead to increases in public expenditure under other Acts, in particular under section 225 of the National Health Service Act 2006 which concerns the payment of sums by the Secretary of State to Special Health Authorities. NHS Blood and Transplant is a Special Health Authority and it is anticipated that its costs will increase as a result of the provision made by the Bill.

Compatibility with the European Convention on Human Rights

- 37 This is a Private Member's Bill. Accordingly, a statement of compatibility with the Human Rights Act 1998, in accordance with section 19(1)(a) of that Act, is not required. Nonetheless, in the Government's view, the provisions of the Bill are compatible with the European Convention of Human Rights.
- 38 The Bill provides for a system of 'deemed consent' to organ donation. Consent by an adult will be deemed to be in place unless they made an express decision not to consent, they appointed someone to make the decision on their behalf, an exception applies or there is information that would lead a reasonable person to conclude that they would not have consented.
- 39 Article 3 (Prohibition of inhuman or degrading treatment) could potentially be engaged if, for example, a deceased person's organs are removed and a close relative is unaware or has not had reasonable opportunity to provide information that would suggest the deceased would have in fact objected to the organ donation. However, it is unlikely that there would be any interference due to the exceptions and because close relatives are always consulted before organ donation goes ahead. The Bill is very likely to be compatible with Article 3.
- 40 The right to express consent or refusal in relation to the removal of a spouse's tissue falls within the ambit of Article 8 (Right to respect for private and family life) and if there is a lack of information about deemed consent then Article 8 may be interfered with. However, there will be a year long intensive campaign followed by ongoing communication to ensure the public are familiar with the

law, and there are safeguards in the Bill, thereby reducing the likelihood of any unjustified interference with a person's Article 8 rights.

- 41 Article 9 (Freedom of thought, conscience and religion) may be engaged and deemed consent has the potential to interfere with a person's right to freedom of thought; conscience and religion if those rights were not respected. A person can make their decision to consent or not to consent, can appoint a representative to decide on their behalf, or family or close friends can confirm the wishes of the deceased. These safeguards in the Bill reduce the likelihood of any potential interference with a person's Article 9 rights.
- 42 The provisions of the Organ Donation (Deemed Consent) Bill are considered compatible with ECHR and any interference would be justified as a proportionate means of achieving a legitimate aim.

Related documents

43 The following documents are relevant to the Bill and can be found at the stated locations:

- Department of Health and Social Care, The New Approach to Organ and Tissue Donation: Government response to consultation (5 August 2018) - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/731913/govt-response-organ-donation-consent.pdf;
- Department of Health and Social Care, Impact Assessment: An Opt-out System of Organ and Tissue Donation (5 August 2018) - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/731915/Organ_donation_impact_assessment.pdf;
- Department of Health and Social Care, Introducing an 'Opt-out' Consent for Organ and Tissue Donation in England: consultation document (12 December 2017) - <https://www.gov.uk/government/consultations/introducing-opt-out-consent-for-organ-and-tissue-donation-in-england/consultation-on-introducing-opt-out-consent-for-organ-and-tissue-donation-in-england>; and
- Human Tissue Act 2004 - <http://www.legislation.gov.uk/ukpga/2004/30/contents>.

Annex A – Territorial extent and application in the United Kingdom

- 44 This Bill extends to England, Wales and Northern Ireland. However, the amendments to consent only apply to England. The amendments to the 2004 Act concerning the use and storage of organs and tissue for transplanted purposes applies to both England and Northern Ireland.

Provision	Extends to E & W and applies to England?	Extends to E & W and applies to Wales?	Extends and applies to Scotland?	Extends and applies to Northern Ireland?	Legislative Consent Motion needed?
Clause 1: “Appropriate consent” to adult transplantation activities: England	Yes	No	No	No	No
Clause 2: Consequential amendments	Yes	No	No	Yes	Yes
Clause 3: Extent, commencement and short title	Yes	Yes	No	Yes	No

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