



## EXPLANATORY NOTES

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# Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022

Chapter 10

£6.90



# **ORGAN AND TISSUE DONATION (DEEMED CONSENT) ACT**

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## **EXPLANATORY NOTES**

### **INTRODUCTION**

1. These Explanatory Notes to the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 which received Royal Assent on 30 March 2022. They have been prepared by Department of Health in order to assist the reader in understanding the Act. They do not form part of the Act and have not been endorsed by the Assembly.
2. The Notes needs to be read in conjunction with the Act. They are not, and are not meant to be, a comprehensive description of the Act. So where a section or part of a section or Schedule does not seem to require an explanation or comment, none is given.

### **BACKGROUND AND POLICY OBJECTIVES**

3. The donation or organs and tissues after death helps to save and improve many lives in Northern Ireland each year. Just one donor could transform the lives of up to nine other people. Last year in Northern Ireland there were 51 deceased donors, resulting in 113 transplants throughout the UK. In total, 87 Northern Ireland residents received transplants.
4. There is widespread public support in the United Kingdom 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 transplants from deceased donors have increased by 56%. There are almost 25 million people on the NHS Organ Donation Register (ODR).
5. Despite this, there is a shortage of donors in Northern Ireland, with around 115 people waiting for a transplant. Over half a million people die each year in the UK, but only around 5,000 of those die in circumstances that mean that their organs could be considered for transplantation. Since the introduction of an opt-out system in Wales, consent rates from deceased donors in Wales have increased from 58% in 2015 to 70.7% in 2020. However, the international standard for world class performance is recognised to be an 80% consent rate. This is the target consent rate to which all UK regions have aspired within the current UK-wide strategy (2013-2020). However, the current overall consent rate across the UK (for the year 2019/20) is around 70%. The

consent in Northern Ireland is 64%, and has not increased significantly for several years despite consistently high levels of support for organ donation and consistent growth in registrations on the ODR.

6. Under the current rules in Northern Ireland, a person is considered a possible organ donor following their death if they actively took steps to consent in their lifetime or in the absence of a decision made in life, the family can consent on the patient's behalf.
7. The main policy objective is to increase the current rate of consent in the small number of cases in which it is clinically possible for organ donation to proceed after a person's death. Doing so will increase the overall number of donors, and ultimately the number of lifesaving organs available for transplantation.
8. Whilst a change in the law will not increase the number of cases in which it is clinically possible for organ donation to proceed after a person's death, it has the potential to increase the consent rate in situations where a potential organ donor has been identified. This is generally a person for whom further intensive care has no prospect of bringing about recovery.
9. The Act would change the current system in Northern Ireland, from one where people can choose to 'opt in' or 'opt out' on the ODR, to a new statutory opt-out system in which consent is deemed or presumed except in certain exempt circumstances, or if a person has made a decision to opt out during their lifetime. This is often referred to as "deemed consent".

## **OVERVIEW**

10. The current law on consent for the use of bodies and most human organs and tissue relevant material 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 purposes 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 a child, but, under the 2004 Act as it currently stands, the overarching principle for activities which are to take place after an individual's death is that consent must be given expressly by a decision of the individual which is in force immediately before their death, or by a decision by a person appointed by them or in a "qualifying relationship" with them.
11. The Act amends the 2004 Act to provide that consent to organ and tissue donation in NI will be deemed to have been given by a potential adult organ donor before their death unless that donor had expressly stated that they did not wish to be an organ donor or one of the exceptions applies.

12. This is often referred to as an “opt-out” system of consent as a person will be deemed to have given consent to becoming an organ donor unless they have otherwise indicated. The Act 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)
13. This Act also does not propose any changes to consent concerning transplants from living persons and the consent of the donor will continue to be required in those circumstances. Further, the Act 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. This has been referred to as a “soft opt-out” system as evidence of the known wishes of the deceased person has to be considered in deciding whether consent should be deemed to have been given.
14. The Act also provides exceptions applicable to the following groups of adults, in respect of whom the deemed consent provisions will not apply:
  - People who were short-term visitors or temporarily resident in Northern Ireland for less than 12 months immediately before dying. Examples could include overseas workers, students, overseas Armed Forces personnel; and
  - People who lacked the capability to fully understand the consequences of deemed consent for a significant period before dying.
15. Deemed consent will not apply in respect of all organs and tissues. Organs and tissues that are to be included within deemed consent will be set out in regulations made by the Department.
16. The Act will also amend the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 to extent the Department’s existing statutory duty to report to the Assembly to include, at least once every five years, the opinion of the Department as to whether both the 2016 Act and the new Organ and Tissue Donation (Deemed Consent) Act, have been effective in promoting transplantation. The Act also included a duty on the Department to inform the public at least once a year specifically about deemed consent and how a person can during their lifetime record their own decisions about transplantation after their death of parts of their body, or appoint someone to make decisions after their death about transplantation of parts of their body.

## **COMMENTARY ON SECTIONS**

### **Section 1: “Appropriate consent” to adult transplantation activities: Northern Ireland**

This Section amends section 3 of the 2004 Act to provide that deemed consent of the person concerned amounts to appropriate consent for the purposes of certain transplantation activities unless the person concerned is an excepted adult. This is achieved in particular by the amendment to subsections (6)(ba). By shifting the default position in relation to consent away from an opt-in system to an opt-out one, it is hoped that consent for transplantation in the cases which are clinically suitable will rise towards the target percentage of 80 per cent.

There will be, of course, people who have actively recorded a decision in writing 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 what constitutes “appropriate consent”. The Act also provides that consent cannot be deemed to have been given where a person who stood in a qualifying relationship to the deceased provides information that would lead to a conclusion that the deceased would not have consented to organ donation.

Consent will not be deemed to have been given in cases where the transplantation is of novel material. This is to ensure that the new system of consent is in line with the common understanding of organ and tissue donation. Material that is permitted to be transplanted (permitted material) will be specified in regulations made by the Department following consultation. Regulations made by the Department under the provisions inserted by this Act must be laid in draft before and approved by a resolution of the Assembly.

People who lacked capacity to understand deemed consent for a significant period before their death and those who were not ordinarily resident in Northern Ireland for at least 12 months before dying are excluded from the deemed consent system.

The Section amends section 15 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 to include a duty on the Department to inform the public at least once a year specifically about deemed consent and how a person can during their lifetime record their own decisions about transplantation after their death or parts of their body, or appoint someone to make decisions after their death about transplantation of parts of their body. The Section also amends section 16(3)(a) of that Act to extend the duty of the Department to report the opinion of the Department as to whether that Act has been effective in promoting transplantation to include reporting also on whether this Act has been effective in promoting transplantation.

## **HANSARD REPORT**

17. The following table sets out the dates of the Hansard reports for each stage of the Act's passage through the Assembly and the date Royal Assent was received.

STAGE	DATE
First Stage	5 July 2021
Second Stage	20 September 2021
Committee Stage Report	16 December 2021
Consideration Stage	24 January 2022
Further Consideration Stage	1 February 2022
Final Stage	8 February 2022
Royal Assent	30 March 2022

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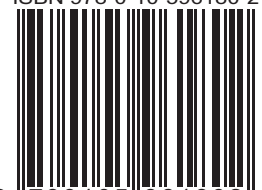
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