

EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE ACT DRAFT CODE OF PRACTICE F, PART TWO: DECEASED ORGAN AND TISSUE DONATION - REVISED 2022

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the Code

- 2.1 The Human Tissue Act 2004 (“the HT Act”) sets up a framework to regulate the storage and use of human organs and tissues from the living, and the removal, storage and use of tissues and organs from the deceased, for specified health related purposes and public display. The HT Act establishes a regulatory authority, the Human Tissue Authority (“HTA”), which regulates these activities.
- 2.2 Section 26(1) of the HT Act provides that the HTA may prepare and issue codes of practice for giving practical guidance to persons carrying on activities with the HTA’s remit as well as laying down the standards expected in relation to the carrying-on of such activities.
- 2.3 The Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 is intended to come into force in Spring of 2023. It will amend the definition of ‘appropriate consent’ as set out in the HT Act for Northern Ireland and introduce a deemed consent system for deceased organ and tissue donation.
- 2.4 Following consultations with stakeholders, Code of Practice F, Part Two: Deceased Organ and Tissue Donation (“the Code”) has been reviewed and amendments have been made to reflect the changes relating to deemed consent in Northern Ireland. The revised Code will provide updated guidance to clinical staff who seek consent for deceased organ and tissue donation.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

4. Extent and Territorial Application

- 4.1 The territorial extent of this Code of Practice is England and Northern Ireland.
- 4.2 The territorial application of this Code of Practice is England and Northern Ireland.

5. European Convention on Human Rights

- 5.1 As the Code of Practice is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 Section 26 of the HT Act gives the HTA power to prepare, issue and publish Codes of Practice for activities within its remit. Sections 26 and 27 of the HT Act also require the HTA to lay down standards for obtaining consent for activities under the Act.

- 6.2 Section 29 of the HT Act sets out that before being issued, the Codes of Practice must be approved by the Secretary of State and laid by him before both Houses of Parliament and that a 40-day period has elapsed without either House resolving not to approve the draft. The Code can then come into effect on a day appointed in directions made by the HTA.
- 6.3 The Code forms part of the regulatory system established under Part 2 of the HT Act. Section 26(4) of the Act requires the HTA to keep any Code of Practice issued under Section 26 under review and prepare a revised Code of Practice when appropriate.
- 6.4 The Code updates and replaces the Code laid before Parliament in 2020, in accordance with Section 26(4) of the HT Act. The Secretary of State has approved the Code following consultation the relevant Northern Ireland department, and laid it before Parliament in accordance with Section 29 of the Act.

7. Policy background

What is being done and why?

- 7.1 The Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 was passed by the Northern Ireland Assembly in February 2022 and received Royal Assent on 30 March 2022. This Act, when it comes into force in Spring 2023, will amend the definition of ‘appropriate consent’ as set out in the HT Act for Northern Ireland and introduce a deemed consent system for deceased organ and tissue donation. Because the Act will introduce deemed consent in Northern Ireland, the HTA agreed with the Department of Health in Northern Ireland to amend the Code to reflect the changes relating to deemed consent.
- 7.2 In Wales, the Human Transplantation (Wales) Act 2013 introduced deemed consent for deceased organ and tissue donation in 2015. Clinicians in Wales follow the Code of Practice on the Human Transplantation (Wales) Act 2013.
- 7.3 In Scotland, the Human Tissue (Authorisation) (Scotland) Act 2019 introduced deemed authorisation for deceased organ and tissue donation in 2021. The HTA is not responsible for regulating organ and tissue donation in Scotland.
- 7.4 The revised Code of Practice F, Part Two: Deceased Organ and Tissue Donation provides updated guidance to Specialist Nurses involved in organ donation (SNOD), Specialist Nurses involved in tissue donation (SNTD), Specialist Requesters (SR) or other clinical staff who seek consent for deceased organ and tissue donation. Minor revisions are made throughout the text to reflect the introduction of deemed consent in Northern Ireland including the addition of references to Northern Ireland legislation, expanded guidance on concepts including *residency/ordinarily resident*, *capacity/mental capacity*, *excepted adult*, and the use of organs and tissue across borders, and examples illustrating what the revised guidance entails for establishing when consent can be deemed.

Explanations

What did any law do before the changes to be made by this instrument?

- 7.5 The Code provides guidance for clinical staff who seek consent for deceased organ and tissue donation. The guidance set out in the previous version reflected deemed consent for deceased organ and tissue donation in England and the absence of deemed consent in Northern Ireland.

Why is it being changed?

- 7.6 To reflect the introduction of a deemed consent system for deceased organ and tissue donation in Northern Ireland in Spring 2023.

What will it now do?

- 7.7 Provide guidance that reflects that a deemed consent system for deceased organ and tissue donation will be in place in Northern Ireland.

8. European Union Withdrawal and Future Relationship

- 8.1 This Code of Practice does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

- 9.1 This Code replaces the previous version of Code of Practice F, Part Two that the Human Tissue Authority published in 2020.

10. Consultation outcome

- 10.1 Under section 26(5) of the Act, the HTA is required to consult such persons as it considers appropriate before producing its Codes of Practice. The HTA held a public consultation from 6 May to 24 June 2022 and six roundtable events with stakeholders inviting them to comment on the revisions to the Code. At each event they presented an overview of, and rationale for, the proposed changes. Information about the proposed changes to the Code, a copy of the revised draft Code and a survey were added to the HTA website to broaden the engagement on their proposals. Direct communications about the consultation were sent to stakeholders across the UK to encourage engagement and provide those with an interest the opportunity to respond.
- 10.2 The feedback received was positive, stating the Code is very clear and helpful. Stakeholders found the scenario examples helpful and requests were made for additional examples to address Northern Ireland specific challenges regarding cross-border working and residency. These were shared and shaped with input from key operational stakeholders in Northern Ireland and included in the revised Code.
- 10.3 The devolved administration of Northern Ireland has been consulted on the proposed changes and have confirmed they are content.

11. Guidance

- 11.1 No additional guidance is required.

12. Impact

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies.
- 12.2 The impact on the public sector will be limited to clinical staff in Northern Ireland who seek consent for deceased organ and tissue donation, who will be expected to comply with this Code of Practice.
- 12.3 An Impact Assessment has not been prepared as the Code updates existing guidance and has a low level of impact.

13. Regulating small business

- 13.1 The guidance in the Code does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

- 14.1 Section 26(4) of the Act requires the HTA to keep its Code of Practice under review.
- 14.2 The HTA will continue to keep the Code of Practice under review and will revise the Code when appropriate. Before preparing revised Codes of Practice, the HTA will consult such persons as it considers appropriate.

15. Contact

- 15.1 Dylan Parrin at the Department of Health and Social Care Telephone: 07842 321571 or email: dylan.parrin@dhsc.gov.uk can be contacted with any queries regarding the Code.
- 15.2 Maria Nyberg, Deputy Director for Health Ethics, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 James Morris, Minister for Primary Care and Patient Safety at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.