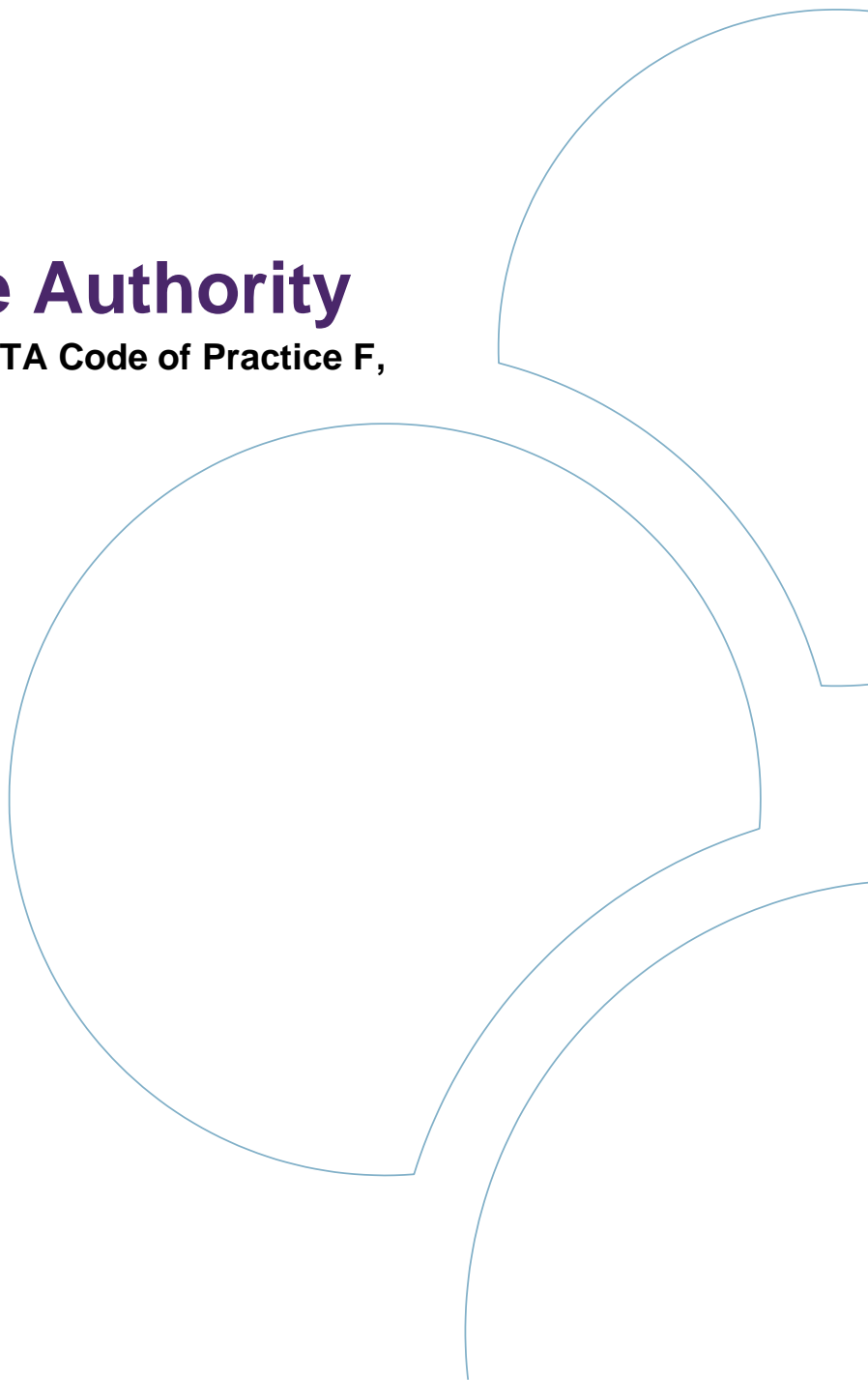


Human Tissue Authority

Consultation response on HTA Code of Practice F,
Part two



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Background to the consultation

1. The Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 (The NI Act) was passed by the Northern Ireland Assembly in February 2022 and received Royal Assent on 30 March 2022. The Act came into force on 1 June 2023 and will amend the definition of 'appropriate consent' as set out in the Human Tissue Act 2004 for NI and introduce a deemed consent system for deceased organ and tissue donation in NI.
2. The NI Act will only apply to 'permitted material' as defined by the Department of Health in NI drafted Regulations, which will specify the material which is not covered by deemed consent. The Regulations will be subject to Parliamentary approval.
3. The Code, which applies to deceased organ and tissue donation, has been amended to reflect the changes to the law in NI. The Code now provides advice and guidance to transplant practitioners in NI and England on how the changes to the law in NI will affect their practice, providing specific guidance for Specialist Nurses in Organ Donation (SNODs), Specialist Requesters and others who seek consent for deceased organ and tissue donation.
4. The Code sets out the circumstances in which a person's consent may be deemed in both England and NI.
5. This document summarises the responses to the HTA's consultation on revisions made to Code of Practice F, Part two.
6. The consultation opened on 6 May 2022 and closed on 24 June 2022 to allow all interested parties an opportunity to respond.

The consultation

7. Under section 26(5) of the Human Tissue Act 2004, the HTA is required to consult before producing its Codes of Practice.
8. The consultation consisted of 7 questions, which are listed below. If the respondent selected "no" to any questions, there was a follow up question to understand the reasons for this.
 1. *Are the updates to the Code to reflect the system of deemed consent in Northern Ireland clear?*
 2. *Are the examples in the Code helpful to practitioners in understanding deemed consent in Northern Ireland?*

3. *Does the Code make clear in which situations consent may be deemed in Northern Ireland?*
 4. *Do you think, where deemed consent is a possibility, the Code provides sufficient clarity about who can provide this information?*
 5. *Are the steps that the Specialist Nurses for Organ Donation/Specialist Requesters working in Northern Ireland would need to take to assess the information clear?*
 6. *Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident Northern Ireland?*
 7. *Is there anything else you would like to specifically draw our attention to with regards to the changes made to Code F in relation to deemed consent in Northern Ireland?*
9. A total of 77 people were invited to roundtable events, of which 23 people attended. 262 direct communications were sent to stakeholders inviting them to participate in the consultation via the survey on the HTA website.
 10. Attendees at the roundtable events and respondents to the consultation included a wide range of clinicians, SNODs, charity representatives, faith organisations, professional bodies, academics and members of the public.

Engagement

15. The consultation was primarily aimed at professionals who would be using the Code of Practice on a day-to-day basis, although members of the public were welcome to respond.
16. A wide range of key stakeholders and organisations across the UK were notified by direct communications about the consultation, encouraging engagement and providing those with an interest the opportunity to respond. This included professional stakeholders, key charities and faith groups.
17. Information regarding the consultation was available to both the public and professionals on the HTA website. Information was included in the HTA professional e-newsletter in March 2022 and shared on social media.
18. Social media sites including LinkedIn and Twitter were utilised to post reminders throughout the consultation period. Overall, 21 re-tweets, 20 'likes' and 2 mentions were received during the consultation period.
19. The format of the consultation included direct communications to stakeholders, which included a link to the HTA website and a Microsoft Forms (MS) survey. In addition, a series of stakeholder roundtable events were held

between 10 and 18 May 2022. Invites were sent to colleagues in the Devolved Administrations, the Clinical Advisory Group (CAG) for NI deemed consent, and other relevant stakeholders in NI, as well as the rest of the UK. These events provided an additional opportunity to discuss the changes being made to the Code.

20. Social media was also used to raise awareness of the consultation. On the day of the launch, three weeks after the start and with one week remaining, social media messages and direct communication reminders were issued, encouraging stakeholders to respond to the consultation.
21. Some stakeholders suggested other changes to the Code could be useful. These were outside the scope of this consultation but were noted for consideration for future revisions of the Code for which separate and specific public consultations would be held.
22. The HTA attended the Clinical Advisory Group meeting on 24 February 2022. This was to provide awareness of the scope of the revisions being planned to be made to the Code of Practice the planned public consultation.
23. The HTA liaised closely with Department of Health NI, DHSC policy and legal colleagues leading up to, during and after the consultation. Specialist advice on technical aspects was sought from professionals including members of the CAG in NI, SNODs, clinicians and NHSBT.

Overview

24. A list of organisations invited to attend roundtable events and notified of the consultation is provided in [Annex A](#). A list of organisations that attended the roundtable events or provided their identity when responding to the survey is at [Annex B](#). Where individuals opted to have their details remain confidential these are listed as anonymous.
25. The HTA is very grateful to those individuals and organisations that responded to the consultation and participated in the roundtable events. All responses have been carefully considered and, where appropriate, amendments have been incorporated into the revised Code of Practice.
26. The responses received via the MS forms survey to each question are included below:

Are the updates to the Code to reflect the system of deemed consent in Northern Ireland clear?

Yes	No
5	1

Are the examples in the Code helpful to practitioners in understanding deemed consent in Northern Ireland?

Yes	No	Partially
5	0	1

Does the Code make clear in which situations consent may be deemed in Northern Ireland?

Yes	No	Maybe
6	0	0

Do you think, where deemed consent is a possibility, the Code provides sufficient clarity about who can provide this information?

Yes	No
6	0

Are the steps that the Specialist Nurses for Organ Donation/Specialist Requesters working in Northern Ireland would need to take to assess the information clear?

Very clear	Mostly clear	Partially clear	Not clear
3	3	0	0

Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident Northern Ireland?

Yes	No	Other
6	0	0

Is there anything else you would like to specifically draw our attention to with regards to the changes made to Code F in relation to deemed consent in Northern Ireland?

Feedback received for this question is summarised in the key themes section below.

Key feedback themes from the consultation

27. The consultation identified some areas where further clarity and review was needed. Specifically, there was comprehensive feedback received on:

- understanding of “ordinarily resident”;
- relevant NI specific legislation to reference;
- advice to restructure some paragraphs and content for clarity;
- advice to remove repetition and text that reduced clarity; and,
- a desire for there to be more working examples.

Changes made to the Code of Practice as a result of the consultation

28. Changes were made to the content of the Code as a result of the feedback received.
29. Feedback during the consultation was very positive, stating the Code was very clear and helpful. Scenario examples were identified as being very helpful and requests were made for additional examples to be included. However, feedback was received about how certain sections of the Code could be modified to improve clarity.
30. Additional examples have been added and others changed in response to specific feedback received.
31. Some paragraphs have been reworded to improve clarity and areas of duplication have been removed.

Ordinarily resident

32. Some respondents felt the paragraphs in this section required additional detail on the requirements for a person to be identified as ordinarily resident in a country. The paragraphs relating to ordinarily resident and the meaning in the glossary has been expanded to improve clarity.
32. Feedback was received requesting additional scenario examples to address the NI specific challenges of cross-border working and residency. Additional examples, specific to these scenarios, were drafted and shared with professional stakeholders, including those from NHSBT, clinicians and SNODs, for comment.
33. The number of examples included in the Code has increased from nine to thirteen.
34. Flowchart B of Annex A was modified to separate NI and England to mitigate the risk associated with deemed consent being applicable in both countries

but only applying when the person who has died is ordinarily resident in the country of their death.

Mental capacity

32. Feedback was received about the appropriate legislation to be referenced when referring to the mental capacity of the donor. These sections were reviewed and amended to reference the appropriate NI legislation.

Additional areas of change as a result of consultation feedback

- The explanation for the term excepted adult in part A was rephrased to improve clarity.
- Flowchart B was updated to improve ease of use and clarity on when deemed consent will apply versus when expressed consent must be sought for organ and tissue donation to proceed.
- Amendments have been made throughout the Code to reflect the change in the law in NI, including NI where it had previously been excluded when referring to deemed consent.
- Two paragraphs were combined and amended to remove repetition and improve clarity on the use of organs and tissue across borders.
- Place holders for pending documents and legislation were added to the relevant points within the text.

Milestones

33. Version two of Code of Practice F, Part two completed the Parliamentary procedure on 7th November 2022.

34. The revised final Code of Practice has been published alongside this document on the HTA website.

35. Version two of Code of Practice F, Part two came into force on 1 June 2023

Annex A: List of organisations notified of the consultation

Organisation/stakeholder
Academy of Medical Royal Colleges
Academy of Medical Sciences
ACLT
Advisory Committee on the Safety of Blood, Tissues and Organs
Age UK
Alzheimer's Research UK
Alzheimer's Society
Anscombe Bioethics Centre
Anthony Nolan
Association of Anatomical Pathology Technology
Association of Medical Research Charities
Association of Paediatric Anaesthetists of Great Britain and Ireland
Association of Paediatric Emergency Medicine
University Hospitals Association
BHF Scotland
BHF Wales
BLISS
Bloodwise
British Association of Critical Care Nurses
British Association for the Study of the Liver
British Association for Nursing in Cardiovascular Care
British Heart Foundation
British Heart Foundation Northern Ireland
British Liver Trust

British Lung Foundation
British Medical Association
British Medical Association Ethics Committee
British Paediatric Respiratory Society
British Psychological Society
British Renal Society
British Transplantation Society
Cancer Research UK
Care Quality Commission
Chief Coroner's Office
Chief Medical Officer
Children's Commissioner for England
Children's Heart Federation
Children's Liver Disease Foundation
Citizens Advice
CLIC Sargent
Coroners' Society of England and Wales
DKMS
Donor Family Network
Epilepsy Society
Faculty of Forensic and Legal Medicine
Faculty of Intensive Care Medicine
Faculty of Public Health
Fight for Sight (UK)
Foundation for Liver Research
General Medical Council

Give A Kidney
Haemochromatosis UK
Health Education England
Health Foundation
Health Research Authority
Healthwatch UK
Heart of Scotland
Heart Research UK
Hospice UK
Human Fertilisation and Embryology Authority
Independent Cancer Patients' Voice
Institute of Biomedical Sciences
Intensive Care Society
Kidney Cancer UK
Kidney Kids Scotland
Kidney Research UK
Kidney Wales
King's Fund
Live Life, Give Life
Liver4life
Living Well, Dying Well
Macmillan Cancer Support
Macular Society
Marie Curie
medConfidential
Medical Research Council

Medical Research Foundation
Medical Research Scotland
Medicines and Healthcare Products Regulatory Agency
Multiple Sclerosis Society
National Kidney Federation
National Voices
NHS Blood and Transplant
NHS Employers
NHS England
National Institute for Health and Care Excellence
National Institute for Health and Care Research
Northern Ireland Kidney Research Fund
Nuffield Council of Bioethics
Nursing and Midwifery Council
Parkinson's UK
Patient Information Forum
Polycystic Kidney Disease UK
Primary Sclerosing Cholangitis (PSC) Support UK
Rare Disease UK
Rainbow Trust Children's Charity
Renal Association
Royal College of Anaesthetists
Royal College of Emergency Medicine
Royal College of GPs
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists

Royal College of Ophthalmologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians and Surgeons of Glasgow
Royal College of Physicians of Edinburgh
Royal College of Physicians of London
Royal College of Radiologists
Royal College of Surgeons of Edinburgh
Royal College of Surgeons of England
Royal National Institute for Blind People
Royal Society of Medicine
Scope
Scottish Government
Sense
Sickle Cell Society
Sue Ryder
Team Margot
The Scottish Cancer Foundation
Thomas Pocklington Trust
Together For Short Lives
Transplants Patients Trust
Wales Kidney Research Unit
Wellcome Trust
Welsh Assembly
Belfast City Council - Migrant Forum
Northern Ireland Strategic Migration Partnership

Migrant and Minority Ethnic Council
Migrant Centre Northern Ireland (Belfast)
Migrant Centre Northern Ireland (North West)
Northern Ireland Council for Racial Equality
Northern Ireland Community of Refugees and Asylum Seekers
Northern Ireland Strategic Migration Partnership
The Executive Office
Department for the Economy Northern Ireland
Department for Infrastructure Northern Ireland
Department of Agriculture, Environment and Rural Affairs Northern Ireland
Department of Education Northern Ireland
Department of Health Northern Ireland
Department of Justice Northern Ireland
Northern Ireland Council for Voluntary Action
Red Cross, Refugee Support
National Society for the Prevention of Cruelty to Children
Belfast Health and Social Care Trust
Children and Young People's Strategic Partnership
Community Development and Health Network
Chinese Welfare Association
South Belfast Roundtable
Inter Ethnic Forum
Stronger Together
Education Authority Northern Ireland
Southern Health and Social Care Trust – Northern Ireland New Entrant Service

Southern Health and Social Care Trust
African and Caribbean Support Northern Ireland
The Resource Centre
Bryson Charitable Group Northern Ireland
Community Intercultural Programme Northern Ireland
Patient Client Council Northern Ireland
Regional Minority Ethnic and Migrants Steering Group
Northern Ireland Civil Service, Racial Equality Group
Chinese Welfare Association Northern Ireland
NI Refugee Resettlement Scheme
Northern Ireland Council for Voluntary Action
Northern Ireland Council for Voluntary Action, Flourish
Evangelical Alliance Northern Ireland
The Methodist Church in Ireland
Church of Ireland
Presbyterian Church Ireland
Association of Baptist Churches in Ireland

Annex B: List of respondents to the consultation

Organisation/Individual	Role
Government of Wales	Member of Value Based Healthcare Policy Team
Department of Health and Social Care	Team Leader, Human Tissue Policy and Ethics of Consent
Department of Health and Social Care	Senior Policy Manager – Health Ethics, Human Tissue Policy
British Medical Association	Head of Medical Ethics
British Medical Association	Senior Public Affairs Advisor
Donate4Dáithí Campaign	
Public Health Agency (NI)	Organ Donation Promotion Manager
The Western Health and Social Care Trust	Assistant Director of Acute Services (Nursing)
Department of Health (NI)	Policy lead in Secondary Care Policy and Legislation
Department of Health (NI)	Chair Health and Social Care Ethics Forum Department of Health
Department of Health (NI)	Head of Organ Donation Bill Team
Northern Ireland Kidney Patients Association	Co-chairperson
Royal Victoria Hospital Liver Support Group	Chairman
The Northern Ireland Kidney Research Fund	Chair
The Northern Ireland Public Health Research Network	Director
NHS Blood and Transplant	Regional Manager

NHS Blood and Transplant	Team Manager
Belfast Health and Social Care Trust	Intensive Care Consultant and Regional Clinical Lead for Organ Donation
Belfast Health and Social Care Trust	Intensive Care Consultant and Educational Clinical Lead for Organ Donation
NHS Blood and Transplant	Head of Education
NHS Blood and Transplant	Legislation Lead
Chief Rabbi's Office	Director of External Affairs
Church and Society Commission Church of Ireland	Acting Chair of the Church and Society Commission
Anonymous	
Anonymous	
Anonymous	
Anonymous	
Anonymous	
Anonymous	