



# Human Tissue Authority

Consultation response on Part Two of Code of Practice F  
Donation of solid organs and tissue for transplantation

20 May 2020

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## Background to the consultation

1. The Organ Donation (Deemed Consent) Bill 2017-2019 received Royal Assent on 15 March 2019. The [Organ Donation \(Deemed Consent\) Act 2019](#) (the Deemed Consent Act) came into force in England on 20 May 2020.
2. The Deemed Consent Act only applies to 'permitted material'; the Department of Health and Social Care (DHSC) has drafted Regulations, which specify the material which is not covered by deemed consent. The Regulations will be subject to Parliamentary approval.
3. Code of Practice F has been amended to provide advice and guidance to transplant practitioners in England on how changes to the new system will affect their practice. This sets out the circumstances in which a person's consent may be deemed.
4. The revised Code of Practice is divided into two parts. Part one which applies to living organ donation and Part two which applies to deceased organ and tissue donation. Part two provides specific guidance for Specialist Nurses in Organ Donation (SNODs), Specialist Requestors and others who seek consent for deceased organ and tissue donation.
5. This document summarises the responses to the HTA's consultation on Part two of Code of Practice F: Donation of solid organs and tissue for transplantation.
6. The consultation opened on 4 July 2019 and closed on 26 September 2019 to allow all interested parties twelve weeks 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. A wide range of key stakeholders and organisations were notified of the consultation and invited to respond. This included Members of Parliament and Peers with a known interest in organ donation and transplantation, professional stakeholders, key charities and faith groups.
9. The main format of the consultation was a survey via Survey Monkey with a series of questions, accessible via the HTA website. Respondents also submitted written responses directly to the HTA.
10. The Department for Health and Social Care (DHSC) leads on changes to legislation associated with organ and tissue donation. NHS Blood and Transplant (NHSBT) is the operational body that run the national organ and tissue retrieval and transplantation service. The HTA's role is to ensure that professionals operating in the donation and transplantation sector understand the law and act within it.
11. The HTA was therefore unable to accept feedback on the merits of the law change itself and these comments were disregarded.
12. The consultation consisted of 10 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. *Is the Code clear?*
  2. *Are the examples in the Code helpful to practitioners?*
  3. *Does the Code make clear in which situations consent may be deemed?*
  4. *Is the role of the family clear within the Code?*
  5. *Are considerations around faith and culture captured appropriately within the Code?*
  6. *Do you think, where deemed consent is a possibility, the Code provides sufficient clarity about who can provide this information?*
  7. *Are the steps that the Specialist Nurses for Organ Donation/Specialist Requesters would need to take to assess the*

*information clear?*

8. *Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident in England?*

9. *Is there any information that should be included in the Code that is currently missing?*

10. *Is there anything else you would like to specifically draw our attention to?*

13. A total of 75 complete responses were received. 60 of these were complete survey monkey responses and 15 were written responses received via email. There were 69 incomplete survey monkey responses received. Where relevant, comments from the incomplete responses were taken into consideration.
14. Respondents were asked if they were responding in a professional capacity, on behalf of an organisation or as a member of the public. Respondents also had the option to submit their contact details or remain anonymous.
15. Of the complete responses, 42% of respondents were professionals, 37% were responding on behalf of an organisation and 21% of respondents were members of the public.
16. Respondents included a wide range of clinicians, SNODs, transplant surgeons, charity representatives, faith and secular organisations, professional bodies, academics and members of the public.

## Engagement

17. 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. Targeted emails were sent to key stakeholders to notify them of the consultation and to advise them on how to respond.
18. The Chief Executive of the HTA held several face-to-face meetings with a variety of stakeholders to discuss the Code of Practice. This allowed for the opportunity to receive and respond to feedback and answer questions that arose during the consultation.
19. The HTA hosted a roundtable event on 25 February 2019 with 24 representatives of faith, secular, and cultural groups. The purpose of the event was to seek views on how conversations with a potential donor's relatives could continue to be conducted in the most sensitive manner,

taking religious and cultural views and traditions into account. Colleagues from NHSBT, the Welsh NHS, and DHSC also attended.

20. A professional stakeholder workshop was held on 7 October 2019. The purpose of the workshop was to engage with frontline professionals who will be required to use the Code of Practice. Delegates included SNODs, Regional Managers, Specialist Requesters, Clinical Leads for Organ Donation (CLODs), and NHSBT tissue services.
21. The HTA participated in NHSBT's Organ Donation Campaign Advisory Group and Organ Donation Legislation Change meetings. This was to provide advice and guidance, where appropriate, to NHSBT on their public awareness campaign, which launched on 25 April 2019.
22. The HTA also participated in regular partnership meetings with NHSBT to provide updates and hear about training development plans for the NHSBT workforce.
23. The HTA liaised closely with DHSC policy and legal colleagues during and after the consultation. Specialist advice on technical aspects and clinical accuracy was sought from professionals including CLODs, SNODs, the NHSBT Organ Donor Register (ODR) team, intensivists, and transplant colleagues from Wales.
24. Information regarding the consultation was available to both the public and professionals on the HTA website. Information was included in the HTA professional e-newsletters in May 2019, July 2019 and September 2019 and shared on social media. A specific blog post was published during the consultation.
25. Social media sites including LinkedIn and Twitter were utilised to post reminders throughout the consultation period. Overall, 223 re-tweets, 167 'likes' and 58 mentions were received during the consultation period.

## Overview

26. A list of organisations invited to respond is provided at Annex A. A list of organisations that responded is at Annex B. Where individuals opted to have their details remain confidential these are listed as anonymous.
27. The HTA is very grateful to those individuals and organisations that responded to the consultation. All responses have been carefully considered and, where appropriate, amendments have been incorporated into the revised Code of Practice.

28. The responses received via survey monkey to each question are included below:

*Is the Code of Practice clear?*

Yes	No	Did not answer
45 (75%)	15 (25%)	0

*Are the examples in the Code of Practice helpful to practitioners?*

Yes	No	Did not answer
46 (76.6%)	7 (11.67%)	7 (11.67%)

*Does the Code of Practice make clear in which situations consent may be deemed?*

Yes	No	Did not answer
45 (75%)	11 (18.33%)	4 (6.67%)

*Is the role of the family clear within the Code of Practice?*

Yes	No	Did not answer
36 (60%)	18 (30%)	6 (10%)

*Are considerations around faith and culture captured appropriately within the Code of Practice?*

Yes	No	Did not answer
43 (71.67%)	10 (16.67%)	7 (11.67%)

*Does the Code of Practice make clear how practitioners will decide whether a person is ordinarily resident in England?*

Yes	No	Did not answer
49 (81.67%)	5 (8.33%)	6 (10%)

*Where deemed consent is a possibility, does the Code of Practice provide sufficient clarity about who can provide information that a person would not have wanted to be a donor?*

Yes	No	Did not answer
44 (73.33%)	10 (16.67%)	6 (10%)

*Are the steps that the Specialist Nurses for Organ Donation /Specialist Requesters would need to take to assess the information clear?*

<b>Yes</b>	<b>No</b>	<b>Did not answer</b>
42 (70%)	9 (15%)	9 (15%)

*Is there any information that should be included in the Code of Practice that is currently missing?*

*Is there anything else to which you would like to specifically draw our attention?*

Feedback received for these two questions is summarised in the key themes section below.

### **Key themes of the consultation**

29. The consultation demonstrated several areas where extensive revision was required. Specifically, there was comprehensive feedback received on:
- The role of the family;
  - Faith and cultural considerations;
  - Advice to clarify specific terminology used throughout;
  - Advice to restructure some paragraphs and content for clarity;
  - Advice to remove repetition and text that did not add value; and
  - A desire for there to be more working examples.

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

30. A number of changes to content have been made to the Code of Practice as a result of the feedback received. In addition, changes have been made to correct typographical errors and clarify sections where information was less clear.
31. A significant number of responses highlighted that the Code of Practice was user friendly. However, extensive feedback about how it could be improved in terms of structure and content was received.
32. The order of the Code of Practice has been amended to ensure the flow of information is as logical as possible. The order follows the donation pathway



as far as is practicable. Areas of duplication have been reduced or removed entirely.

### **Introduction and interpretation**

33. A new introductory section and a scope section were added which clarify new legal terms introduced by the Deemed Consent Act, along with additional information on the HTA's remit with regards to organ and tissue donation and transplantation.
34. The interpretation and general guidance section was extensively revised to explain all terms of substance that appear throughout the Code of Practice. In particular, this section refers to the role of the Specialist Nurses and makes clear what is meant by the terms 'family' and 'information'.
35. Terminology that is applicable in a deemed consent scenario including 'ordinarily resident' and 'significant period' were also defined. Any term that is not specifically defined, but where comments were received seeking clarity, have been included in the glossary.

### **Role of the family**

36. Substantial feedback was received on the role of the family in an organ and tissue donation scenario. This has been addressed by providing clarity on what is meant by 'family' at the beginning of the Code of Practice.
37. Some respondents felt that the Code of Practice should make clear the requirement to establish consent before the family is asked to provide information relevant to organ and tissue donation. This section has been re-worked to reflect this.
38. Some feedback stated that paragraphs in this section could be read in contradiction to each other and have therefore been revised for clarification.
39. The position when there is no family for professionals to speak with, in both an expressed consent scenario and a deemed consent scenario, has been outlined in comprehensive detail.

## Faith and beliefs

40. The faith and beliefs title and section was extensively revised. This follows written feedback received during the consultation and the roundtable meeting in February 2019, as well as face-to-face meetings with faith and belief groups held by the Chief Executive.
41. Specific language and tone was sensitively amended. This follows feedback that the Code of Practice should clearly recognise the seriousness and sincerity of people's religious and non-religious beliefs.
42. Feedback was received on appropriate terminology to indicate individuals who may provide support in discussions around faith and beliefs. This has been incorporated.
43. Information regarding special arrangements that some faith and belief groups may have in place, including dedicated telephone helplines, was added.
44. The role of the faith declaration on the ODR has been clearly outlined, as well as the conversations that the SNOD will have with the family in relation to faith and beliefs.

## Additional areas of change as a result of consultation feedback

- Additional specific examples were added, increasing the number of examples from five to nine.
- Flowcharts were added for ease of use.
- A paragraph on the role of the Coroner has been added.
- A section has been added to make clear that deemed consent does not apply to organs and tissue used for research.
- Amendments were made throughout to reflect tissue donation and a new section on tissue donation has been added.
- Amendments were made to make clear that shared decision-making processes with clinical colleagues are in place and that SNODs do not make all decisions in isolation.
- Hyperlinks to relevant documents were added throughout.

## Next steps

45. The Code of Practice received Parliamentary approval on XXX 2020.
46. The revised Code of Practice has been published alongside this document on the HTA website.
47. The Code of Practice came into force on 20 May 2020.

## Annex A: List of organisations notified of the consultation

Organisation/stakeholder
Academy of Medical Royal Colleges
Academy of Medical Sciences
African Caribbean Leukaemia Trust
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
BLISS
Bloodwise
British Heart Foundation
British Heart Foundation Northern Ireland
British Heart Foundation Scotland
British Heart Foundation Wales
British Association for Critical Care Nurses
British Association for the Study of the Liver
British Association for Nursing in Cardiovascular Care
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 Care 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
NHSBT

NHS Employers
NHS England
National Institute for Health and Care Excellence
NIHR INVOLVE
Northern Ireland Kidney Research Fund
Northern Ireland Department of Health
Nuffield Council of Bioethics
Nursing and Midwifery Council
Parkinson's UK
Patient Information Forum
Polycystic Kidney Disease UK
Primary Sclerosing Cholangitis 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, Edinburgh
Royal College of Physicians, London
Royal College of Radiologists
Royal College of Surgeons, Edinburgh
Royal College of Surgeons, 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
Transplant Patients Trust
University Hospitals Association
Wales Kidney Research Unit

Wellcome Trust
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Welsh Assembly
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### Other key stakeholders and organisations notified of the consultation

- Chief Executives and Chairs of professional bodies
- Chief Executives and Chairs of public facing charities and organisations
- Chief Executives and Chairs of Arm's Length Bodies
- Health policy leads at devolved administrations
- Faith, belief, cultural and community groups
- Transplant surgeons and clinicians
- SNODs and CLODs
- HTA advisory group members
- National Organ Donation Committee members
- ODT Named Individuals on HTA licences
- Interested Lords, MPs and Peers

## Annex B: List of respondents to the consultation

Organisation / Individual	Role
Addenbrookes Hospital, Cambridge	Consultant Transplant Surgeon and Designated Individual for HTA Human Application and Organ Donation and Transplant Licences
African Caribbean Leukaemia Trust	Co-founder and Chief Executive
Anonymous	
Anonymous	
Anonymous	
Anscombe Bioethics Centre	Director
Anscombe Bioethics Centre	Director
Anthony Nolan	Senior Quality Manager
Board of Deputies of British Jews	Member of Defence Division
Board of Deputies of British Jews	Government Affairs Officer
Bristol Royal Hospital for Children	Consultant Paediatric Nephrologist
British Heart Foundation	Policy Officer
British Medical Association	Head of Medical Ethics and Human Rights
British Sikh Nurses	Founder
Cardiff and Vale University Health Board	Regional Clinical Lead for Organ Donation South Wales
Cardiff and Vale University Health Board	Consultant Nephrologist
Cardiff University	Lecturer in Islamic Studies
Catholic Bishops' Conference of England and Wales	Research and Policy
Children's Liver Disease Foundation	Information and Research Hub Manager
Church of England: Mission and Public Affairs Council	National Adviser: Medical Ethics and Health and Social Care Policy
Doctor	HTA Independent Assessor
East Suffolk and North Essex NHS Foundation Trust	Consultant Nephrologist
Evelina Children's Hospital, London	Consultant in Paediatric Intensive Care
Forensic Science Regulation Unit (Home Office Science)	Member of Forensic Science Regulation Unit (FSRU), HO
Guy's and St Thomas' NHS Trust	Chaplain
HM Senior Coroner	Chair Medico-legal Committee CSEW
Humanists UK	Campaigns Officer
Independent Cancer Patient's Voice	President
Institute of Biomedical Science	Deputy Chief Executive
Intensive Care Society (Standards and Guidelines Committee)	Standards and Accreditation Manager
Jain and Hindu Organ Donation Steering Group	Chair
Jeevan Organ Blood Donation	Founder
Kidney Care UK	Policy Director
Kings College Hospital, London	Transplant Service Manager



King's College Hospital, London	Consultant Liver Transplant Surgeon
King's College Hospital, London	Consultant Liver Transplant Surgeon
Leeds Teaching Hospitals NHS Trust	Consultant Renal Transplant
Leeds Teaching Hospitals NHS Trust	Consultant Nephrologist
Leeds Teaching Hospitals NHS Trust	Hepatologist
Manchester University NHS Foundation Trust	Consultant Surgeon and Clinical Director
MedConfidential	Coordinator
Myton Hospice	Staff Nurse
National Kidney Federation	Interim CEO
National Organ Donation Committee	Chair
National Organ Donation Committee	Clinical Lead for Organ Donation
NHS	Chaplain/Spirituality and Wellbeing Practitioner
NHS Greater Glasgow and Clyde	Consultant Transplant Surgeon
NHSBT	Specialist Nurse Organ Donation
NHSBT	Accountable Executive, Opt Out Legislation Implementation
NHSBT	Regional Manager
NHSBT	Team Manager
NHSBT	Specialist Nurse Organ Donation
NHSBT	Specialist Nurse Organ Donation
Non-Religious Pastoral Care Network	Member
Nottinghamshire Universities NHS Trust	Staff Nurse
Nuffield Council on Bioethics	Communications Manager
Nursing and Midwifery Council	Standards Development Specialist
Office of the Chief Rabbi	Director of External Affairs
Priory Group	Registered Mental Health Nurse
Queen Elizabeth Hospital, Birmingham	Consultant Liver Transplant Surgeon
Royal College of Emergency Medicine	National Organ Donation Committee, Clinical lead for Organ Donation
Royal College of Nursing	Director of Nursing Policy and Practice
Royal College of Nursing	Professional Lead
Royal College of Ophthalmologists	Head of Professional Support
Royal College of Pathologists	Press and Communications Manager
Scottish National Blood Transfusion Service	Consultant and Clinical Lead, Tissue and Cells
Senior Coroner	Staffs (South) Coroner
South Asian Health Action	Chair
South Tyneside and Sunderland NHS Foundation Trust	Clinical Lead Organ Donation
South West Transplant Centre	Director of Transplantation
Team Margot Foundation	Chief Executive Officer and Trustee
The National Black, Asian and Minority Ethnic Transplant Alliance	Co-Chair
The Renal Association	Consultant Nephrologist and Renal Association Member
Womb Transplant UK	Chairman

