

Consent/Authorisation for Organ and/or Tissue Donation

This Management Process Description replaces
POL164/4

Copy Number

Effective 02/05/17

Summary of Significant Changes
Changes led by new HTA Codes and to streamline document
Change of terminology from family/family members/friends to relatives
Addition of the Mental Capacity Act (NI) 2016
Removal of Assistant Nurse Practitioner and Tissue Donor Coordinator

Policy

In the United Kingdom (UK), specific legislation sets out who can provide lawful consent (or 'authorisation' in Scotland) for organ and/or tissue donation. The consent/authority or refusal to give consent/authorisation, of the individual expressed in life take priority over any wishes expressed by the relatives after the person has died. In England and Northern Ireland, the relevant legislation is the Human Tissue Act 2004 (HT Act), in Wales the Human Transplantation (Wales) Act 2013, (HT (W) Act) with the Mental Capacity Act 2005 also legislating for England and Wales **and The Mental Capacity Act (NI) 2016**. In Scotland, the relevant legislation is the Human Tissue (Scotland) Act 2006 (HT Scotland Act) the Adults with Incapacity (Scotland) Act 2000 and the Children (Scotland) Act 1995; the HT Scotland Act requires authorisation to be given, rather than consent, for organ and/or tissue donation.

Consent or authorisation is required for organ and tissue donation under this legislation; therefore the Specialist Nurse-Organ Donation (SNOD), Nurse Practitioner (NP) Tissue Donor Co-ordinator- where applicable - must ensure that they understand the requirements of legislation pertinent to their geographical area.

For consent or authorisation to be valid it must be given voluntarily by an appropriately informed person who has the capacity to understand and agree to the activity of organ and/or tissue donation. The consent/authorisation process should follow consistent national practice, based on the specific training undertaken by the SNOD/NP. Information provided during the consent/authorisation conversation should be supported by written information tailored to meet the needs of the relatives.

Purpose

The purpose of this policy is to detail the responsibility of the SNOD/NP when ascertaining consent/authorisation for organ and/or tissue donation.

Responsibilities

Specialist Nurse – Organ Donation/ Nurse Practitioner/Tissue Donor Co-ordinator

To access the NHS Organ Donor Register (ODR) and identify any recorded donation decision of the patient. Following this the SNOD will speak to the relatives and discuss organ and/or tissue donation to ascertain consent/authorisation if appropriate.

Team Manager/Nurse Practitioner

To support the SNOD/ANP in the consent/authorisation process as required.

Regional Manager/National Referral

To support the SNOD/TM/NP/ANP in the consent/authorisation process as required.

Centre Deputy Manager

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National Referral Centre Manager

To support the NRCDM and NRC Nurses in the consent process as required.

Head of Education and Professional Development

To ensure that the policy is implemented and monitored, with appropriate education and training packages in place to maintain quality and standards of practice pertaining to consent and authorisation.

Definitions

Relatives- refers to the spouse, partner and, in cases where there are no relatives, close friends of the deceased person

Appointed/Nominated representative- A person appointed by the patient in life to make a decision on their behalf in regard to organ donation.

SNOD – for the purposes of this document the terminology "SNOD" will apply to Specialist Nurse, Specialist Requester (SR) or Nurse Practitioner (NP)/ Tissue Donor Coordinator (TDC) with the relevant knowledge, skills and training in organ and/or tissue donation, working within NHSBT.

NP- Nurse Practitioner Tissue Services is a practitioner with the relevant knowledge, skills and training in tissue donation working within NHSBT tissue services in England, Wales and Northern Ireland.

TDC - Tissue Donor Coordinator is a practitioner with the relevant knowledge, skills and training in tissue donation working within Scottish National Blood Transfusion Service (SNBTS) in Scotland./NP

Deemed Consent (criteria applies- only in Wales)- means that when there is no record of a person's decision on organ donation, their consent to organ donation will be deemed to have been given, unless a person with a close relationship provides evidence that the person would not have wanted to be an organ donor.

Excepted Adult- An adult who:

- had lived in Wales for less than 12 months at the time of death.
- had lived in Wales for 12 months or more, but were not ordinarily resident in Wales.
- lacked mental capacity to understand the notion of deemed consent for a significant period before their death.

HT Act –requires "appropriate consent" for the removal and use of organs and tissue in England, Wales and Northern Ireland for transplantation. This legislation provided the impetus to change the role of the Organ Donor Register from a largely marketing tool to a consistent operational tool.

HT (W) Act – requires "appropriate consent" for the removal and use of organs and tissue for transplantation in Wales.

HT Scotland Act- requires 'authorisation' for the removal and use of an organ for transplantation.

NRCM-National Referral Centre Manager line manages the NRCDM.

Sequence of Escalation for ANP/NP Managerial Support:

1. Notification of Nurse practitioner
2. Notification of National Referral Centre Deputy Manager.
3. Notification of National Referral Centre Manager

Relevant Information- is any information offered by the relatives that might come to light during the donation conversation that suggests the patient changed his or her mind about their decision to donate any or all organs or tissue or their decision not to donate any or all organs or tissue

Retraction of patient authorisation by the nearest relative- In Scotland, retraction by nearest relative is unlawful for transplant but permissible for other purposes.

Express Consent – The decision of a person when alive to consent or not to consent to certain transplantation activities or the decision of an appointed representative/s on behalf of that person or the decision of someone with parental responsibility (when the person is a child) or the decision of someone in a qualifying relationship with that person.

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Applicable Documents

[MPD901](#) – Approaching Relatives regarding Organ and Tissue Donation

[MPD902](#)- Consent Conversation for Organ and/or Tissue Donation

[FRM4281](#)-Consent/ for Solid Organ and Tissue Donation

[MPD598](#)–Management of the Deceased Donor Relatives Donation Conversation (Scotland)

[FRM1538](#) Authorisation-Solid Organ and Tissue Donation

[MPD875](#) – Patient Assessment (Relatives Conversation)

[FRM4154](#)– Retraction of patient authorisation by nearest relative

[MPD888](#) – Accessing to the ODR

[SOP3817](#) – Access for SNODs to the Organ Donor Register (ODR)

[SOP3649](#)- Voice Recording of Telephone Conversations

[INF1164](#) – Tissue Consent Leaflet

[INF1165](#) – Organ Consent Leaflet

[INF1166](#) – Eye Consent Leaflet

[INF1167](#) – Consent Research Leaflet

[INF1233](#) – Organ Donation Leaflet (Scotland)

[INF1370](#) – Rationale for Authorisation -Solid Organ and Tissue Donation

Human Tissue Authority Codes of Practice

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm>

Requested Allocation of a Deceased Donor Organ

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_114800

HT Scotland Act -

<http://www.legislation.gov.uk/asp/2006/4/contents>

HT Scotland Act-(Explanatory Notes)

<http://www.legislation.gov.uk/asp/2006/4/notes/contents>

Adults with Incapacity (Scotland) Act 2000 -

<http://www.legislation.gov.uk/asp/2000/4/contents>

Children (Scotland) Act 1995-

<http://www.legislation.gov.uk/ukpga/1995/36/contents>

The Quality and Safety of Organs Intended for Transplantation Regulations 2012

HT Act-

<http://www.legislation.gov.uk/ukpga/2004/30/contents>

HT (Wales) Act 2013

<http://www.legislation.gov.uk/anaw/2013/5/contents/enacted>

[http://www.hta.gov.uk/db/documents/HTA_CoP_on_Human_Transplantation_\(Wales\)_Act_2013_-_Final_-_May_2014.pdf](http://www.hta.gov.uk/db/documents/HTA_CoP_on_Human_Transplantation_(Wales)_Act_2013_-_Final_-_May_2014.pdf)

Mental Capacity Act 2005-

<http://www.legislation.gov.uk/ukpga/2005/9/contents>

<http://www.legislation.gov.uk/uksi/2012/1501/contents/made>

Mental Capacity Act (NI) 2016.

<http://www.legislation.gov.uk/nia/2016/18/contents>

The Quality and Safety of Organs Intended for Transplantation – a Documentary Framework

http://www.hta.gov.uk/db/documents/Organs_Intended_for_Transplantation_-_documentary_framework_July_2012.pdf

1. INTRODUCTION:

- 1.1. NHS Blood and Transplant (NHSBT) is a UK wide organisation and, as such, must take into consideration the differing legal systems concerning consent/authorisation across the constituent countries of the United Kingdom. NHSBT as an organisation is responsible for staff working in organ and tissue donation, therefore NHSBT will be required to work to The Quality and Safety of Organs intended for Transplantation Regulations (2012) and associated UK legislation and guidance to ensure the requirements relating to consent/authorisation are met prior to procurement of organs and tissues. This policy outlines the legal and professional responsibilities of the SNOD/NP/TDC when ascertaining consent/authorisation from relatives.
- 1.2. 'Consent' is the term referred to in the HT Act and HT (W) Act (*England, Wales and Northern Ireland*). The HT Scotland Act refers to the term 'authorisation.'
- 1.3. Consent/authorisation for organ/tissue donation must be given without conditions and without financial benefit (DH & NHSBT, 2010).
- 1.4. Within organ and tissue donation, in the circumstances of proposed Donation after Circulatory Death (DCD), where brain injury is not a feature and capacity is retained by the patient, consent/authorisation for organ donation can only be obtained from the patient before planned Withdrawal of Life Sustaining Treatment (WLST).
- 1.5. In all cases of proposed Donation after Brain Death (DBD) and in the majority of proposed DCD cases, if the person has not given consent/authorisation and lacks the capacity to do so, it is not possible to obtain consent/authorisation from the individual therefore any consent/authorisation can be given in keeping with the requirements of the HT Act, HT (W) Act or the HT(S) Act 2006.

2. TELEPHONE CONSENT/AUTHORISATION

- 2.1. It is possible to proceed with organ and/or tissue donation on the basis of telephone consent/authorisation, as it is not a legal requirement to have written consent/authorisation. Documentary evidence of how verbal consent was obtained is a professional requirement of the General Medical Council and Nursing and Midwifery Council.

SECTION A:

3. LEGAL REQUIREMENTS AND FRAMEWORK FOR CONSENT AS PER HT ACT IN ENGLAND, NORTHERN IRELAND AND HT(W) ACT FOR WALES

VERIFYING OR OBTAINING CONSENT FOR DECEASED DONATION

- 3.1. The HT Act and HT (W) Act makes clear that where an adult made a decision to, or not to, consent to organ and tissue donation taking place after their death, then that consent is sufficient for the activity to be lawful.
- 3.2. The SNOD/NP/ TDC must ascertain if the patient has registered a decision regarding organ donation through checking the Organ Donor Register (ODR).
- 3.3. If the patient has registered a decision about organ donation on the ODR but the relatives state, during discussions, that the patient had changed their mind, the relatives must provide the SNOD with 'relevant information' to support this.
- 3.4. This evidence must demonstrate, without doubt, that this latest decision was that of the patient and was more recent than the recorded ODR decision.
- 3.5. The absence of a tick in a box on the ODR operates as a decision by the person not to donate that particular organ/tissue. This decision must be shared with the relatives by the SNOD or another suitably trained member of the Multi Disciplinary Team (MDT).
- 3.6. In the absence of a box to tick, where there was no option for organs/tissue available at the time of ODR registration i.e. not listed on the ODR form then consent can be explored with the relatives.
- 3.7. If consent is established from accessing the ODR, the patient's relatives should be informed at the outset.

4. FIRST PERSON CONSENT

- 4.1. Under the HT Act and HT (W) Act it is lawful to proceed with organ and/or tissue donation where first person consent has been given.
- 4.2. Under the HT (W) Act for patients who live and die in Wales, in the absence of express consent or an appointed representative organ/tissue donation is lawful if carried out with deemed consent unless the person is under 18yrs of age or an Excepted Adult.
- 4.3. If the patient has expressed a decision to donate either verbal or written and the relatives strongly objects to donation, under the HT Act and HT (W) Act it is lawful to proceed. Although the relatives have no legal right to veto the patient's decision, cases need to be considered sensitively and on an individual basis as the HT Act and HT(W) Act codes of practice state that it is not unlawful not to proceed.

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5. NOMINATED/APPOINTED REPRESENTATIVE

- 5.1. A person may, during their lifetime, nominate/appoint someone to make the donation decision for them. This can be recorded on the ODR or in writing; if written this must be signed by the patient in the presence of a witness who confirms the signature on the document. If verbal, two witnesses are required to have been present at the same time.
- 5.2. If there is a nominated /appointed representative to provide consent information to they must be the first point of contact. This will not apply if that person cannot be found or if the timeframe needed for the donation is so limited that it is not reasonably practicable to communicate with that person. N.B. The nominated/appointed representative is **not** the same as the power of attorney.
- 5.3. In the absence of a nominated/appointed representative and where deemed consent would not be applicable the SNOD/NP/ TDC should obtain from the person in the highest ranking 'qualifying relationship', providing adequate information is given, so that an informed decision regarding organ and/or tissue donation can be reached.

6. DEEMED CONSENT (Welsh residents who die in Wales)

- 6.1. The HT (W) Act allows for consent to deceased organ/tissue donation to be deemed to have been given when a person both lived and died in Wales unless the person is either:
 - a) A person aged under 18
 - b) An adult who has lived in Wales for less than 12 months
 - c) An adult who has lived in Wales for more than 12 months but is not ordinarily resident there
 - d) An adult who lacked the capacity to understand the notion of deemed consent for a significant period before their death.
- 6.2. When one of the categories a to d above applies, a person's consent cannot be deemed, and express consent should be established or sought.
- 6.3. Deemed consent means that when there is no record of a persons decision on organ donation, their consent to organ donation will have been deemed to have been given, unless a person with a close relationship provides evidence that the person did not want to be an organ/tissue donor.
- 6.4. In cases where there must be express consent this can mean the decision of the person in life, the decision of an appointed representative, the decision of a person in a qualifying relationship or the decision of a person with parental responsibility in the case of children.
- 6.5. If a person made a decision in regard to organ donation when they were alive, their consent cannot be deemed.

7. CONSENT FOR PAEDIATRIC DONORS

- 7.1. The HT Act and HT (W) Act defines a child as being under the age of 18. The position for a child, who was competent to reach a decision before they died and consent to organ and tissue donation taking place after their death, is legally no different from that of an adult. The child's consent is sufficient to make removal, storage or use of their organs and tissue for transplantation lawful.

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- 7.2. If, in any case where a child has given consent to donation, especially if the child has self-registered on the ODR, it is essential to establish whether the child had capacity to make that decision in his or her lifetime. If the child did not have capacity to make that decision, then discuss this with the child's relatives and take their views and wishes into account before deciding how to proceed.
- 7.3. Where the child did not have capacity to consent, consent for donation can be given by a person who had parental responsibility for the deceased child immediately before he or she died. A person who has parental responsibility will usually, but not always, be the child's parent.
- 7.4. If a child did not make a decision, or was not competent to make a decision the HT Act and HT (W) Act allows the appropriate consent to be given by a person with parental responsibility for the child immediately before they died. The consent of only one person with parental responsibility is necessary.
- 7.5. If there is no person with parental responsibility (e.g. if the parents have also died), then consent for organ and tissue donation should be sought from someone in a qualifying relationship. Under the HT Act, children cannot appoint nominated representatives and therefore provisions relating to seeking consent from nominated representatives do not apply.
- 7.6. A child in Wales under the HT (W) Act can appoint a representative.

8. HIERARCHY OF QUALIFYING RELATIONSHIPS

- a) spouse or partner*;
- b) parent or child**
- c) brother or sister;
- d) grandparent or grandchild;
- e) niece or nephew;
- f) stepfather or stepmother;
- g) half brother or half sister; and
- h) friend of longstanding.

*Partner is someone in an 'enduring family relationship.'

**In this context a child may be of any age

9. CONSENT FOR OTHER SCHEDULED PURPOSES

- 9.1. It must be ensured that consent is ascertained for storage, and other scheduled purposes with the person who is able to make the consent decision.
- 9.2. Deemed consent cannot be applied for other scheduled purposes and express consent must be sought.

10. TISSUE DONATION AND STORAGE OF BLOOD VESSELS, SPLEEN AND LYMPH NODES

- 10.1. Some tissues including those needed to support the transplant process, such as blood vessels, will be retrieved to support surgical procedures. The blood vessels may be stored for a period of 14 days and will be disposed of as per local hospital/tissue establishment policy if not used within that timeframe.

11. OBTAINING CONSENT FOR OTHER SCHEDULED PURPOSES OF AN ORGAN PRIOR TO RETRIEVAL

- 11.1. In the unlikely event that the organs consented for, should not be suitable for transplant after removal they may be offered for research, education, training and audit. The HT Act and HT (W) Act requires that consent for these purposes is in place.
- 11.2. Organs and/or tissues that are not used for a scheduled purpose or following the completion of a scheduled purpose will be disposed of as per local hospital/tissue establishment policy.

12. WITHDRAWAL OF CONSENT FOR ORGAN AND/OR TISSUE DONATION

- 12.1. During the consent conversation the SNOD/ NP/ should inform the relative that if they require any further information or wish to modify their consent this can be done at any time by contacting the SNOD/NP/TDC up until the time that the retrieval of the organ and/or tissue has commenced.

13. WITHDRAWAL OF CONSENT FOR RESEARCH

- 13.1. It is possible to withdraw consent for research up to the point at which donated organs or tissues are used.

14. PROHIBITION OF PAYMENT

- 14.1. The HT Act and HT (W) Act prohibits any reward being offered or accepted in exchange for an organ. In England, Wales and Northern Ireland, no-one is able to offer payment for an organ.

SECTION B:

15. LEGAL REQUIREMENTS AND FRAMEWORK FOR AUTHORISATION HT(S)A 2006

VERIFYING OR OBTAINING AUTHORISATION FOR DECEASED DONATION

- 15.1. The HT(S) Act 2006 makes clear that adults can authorise the removal and use of body parts after their death for the purpose of transplantation, as well as for the purposes of research, education or training or audit.
- 15.2. The SNOD must ascertain if the patient has registered a decision regarding organ donation on the ODR. If the patient is not on the ODR, the SNOD must ascertain if the patient had made their decision known via a donor card/will/or an expressed decision.
- 15.3. If self authorisation is established, the relatives of the deceased should be informed.
- 15.4. If self authorisation cannot be established, the 'nearest relative' or, in the case of children under 16, the person with parental rights and responsibilities should be approached for authorisation.
- 15.5. In the absence of expressed decision/nearest relatives/ friend of longstanding the SNOD should discuss these circumstances at the time with the TM/geographical RM/On-Call RM as donation will not be able to proceed.
- 15.6. If an adult with incapacity has expressed a decision to donate their views should be taken into account as with any other adult. If incapacity was known the relatives should be approached for authorisation.

16. SELF AUTHORISATION

- 16.1. Self authorisation is all that is required for donation for transplantation to be legal.
- 16.2. If self-authorisation was not made in life the nearest relative should be approached for authorisation.
- 16.3. The nearest relative can extend authorisation for transplantation to include education, training, research and audit.

17. AUTHORISATION FOR CHILDREN

- 17.1. Under the HT(S) Act 2006, a child is defined as anyone under the age of 16 years.
- 17.2. Under the HT(S) Act 2006, anyone aged 12 years or older can give self-authorisation.
- 17.3. Children over the age of 16 can give authorisation to donate the organs/tissue of their parent.
- 17.4. If a child has not given self authorisation before death only the person with parental rights and responsibilities in relation to the child (and who is not a local authority) can provide authorisation.
- 17.5. The person with parental rights and responsibilities can also extend authorisation for transplantation to include education, training, research and audit.

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18. HIERARCHY OF THE NEAREST RELATIVE

The nearest relative is the person who immediately before the adult's death was:

- a) the adult's spouse or civil partner;
- b) * person living with the adult as husband or wife or in a relationship which had the characteristics of the relationship between civil partners and had been so living for a period of not less than 6 months (or if the adult was in hospital immediately before death had been so living for such period when the adult was admitted to hospital);
- c) the adult's child;
- d) the adult's parent;
- e) the adult's brother or sister;
- f) the adult's grandparent;
- g) the adult's grandchild;
- h) the adult's uncle or aunt;
- i) the adult's cousin;
- j) the adult's niece or nephew; and
- k) a friend of longstanding of the adult

For the purpose of identifying the nearest relative, the categories of persons listed above rank in the order of that list.

A person can be left out of account if they are (i) under 16; (ii) if they do not wish or are unable to make a decision regarding authorisation; or (iii) it is not reasonably practicable to communicate with them in the time available.

*A partner has to have been living with the deceased in an 'enduring relationship'. The length of that relationship is not specified in legislation but over 6 months is generally accepted.

*Half-blood relatives are treated as whole; a stepchild is treated as a child: spouse or partner removed from hierarchy is permanently separated.

If the adult's spouse or civil partner is permanently separated (either by agreement or under an order of a court or has deserted the adult) they should be disregarded.

19. BEST PRACTICE

19.1. In Scotland legislation allows the SNOD to provide the nearest relative with a level of information that meets with the relatives' requirements, there is no obligation to provide core information.

19.2. The SNOD should, where the relatives wish it discuss the option of organ and or tissue donation in a way that they can understand. The most important part of the donation process is the discussion, information giving and decision-making surrounding authorisation.

19.3. The donation conversation forms part of the process rather than something that happens in isolation. The SNOD must therefore ensure the relatives receive accurate, understandable and consistent information regarding the patient's prognosis.

19.4. The information the SNOD imparts should meet the needs of the relatives, bearing in mind that information can be provided by means other than just verbal communication.

19.5. In circumstances where nearest relatives are providing authorisation on behalf of the patient and the relatives decline to receive information about the donation process, this does not prevent the relatives from giving authorisation.

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- 19.6. The SNOD should ensure that adequate information is provided to the patient's relatives to allow a decision to be made regarding organ and/or tissue donation.
- 19.7. In addition, the person giving authorisation must do so voluntarily and have the capacity to do so. They must also have no actual knowledge that the adult was unwilling for donation to proceed.
- 19.8. If self authorisation does not exist and if the nearest relative has contributed to the death of the donor (e.g. murder or culpable homicide) this may be classed as a form of desertion/separation and authorisation obtained from the nearest relative lower in the hierarchy.
- 19.9. If there is no friend of longstanding but the patient's GP has knowledge of the person's decision to be a donor this may be acceptable.

20. EXTENSION OF AUTHORISATION FOR TRANSPLANTATION TO INCLUDE RESEARCH, EDUCATION, TRAINING OR AUDIT

- 20.1. Registration on the ODR does not include authorisation for storage or research, education, training or audit and these areas must be discussed with the patient's relatives to ascertain their authorisation.
- 20.2. The SNOD should inform the relatives that in the unlikely event that the organs authorised for removal, should not be suitable for transplant after removal they may be offered for research, education, training and audit or disposed of as per HT(S) Act 2006.

21. RETRACTION OF AUTHORISATION (SCOTLAND)

- 21.1. In Scotland, retraction by nearest relative is unlawful for transplant but permissible for other purposes. The SNOD must discuss this point with the patient's relatives in a sensitive manner and document that the conversation has taken place on the authorisation form.
- 21.2. Authorisation can **only** be withdrawn for the other purposes (research, education, training, and audit), but this must be in writing, by completing [FRM4154](#) - Retraction of Authorisation by Nearest Relative.
- 21.3. Retraction for transplantation is unlawful in Scotland if authorisation has already been given.

22. .PROHIBITION OF PAYMENT

- 22.1. The HT(S) Act 2006 prohibits any reward being offered or accepted in exchange for an organ.