MANAGEMENT PROCESS DESCRIPTION MPD902/9

Consent Conversation for Organ and/or Tissue Donation

This Management Process Description replaces MPD902/8

Copy Number

Effective **18/03/2020**

Summary of Significant Changes

Addition of information about the removal of organs for scheduled purposes in hospitals where there is a satellite license for QUOD research in adults aged 18 and over

Addition of SOP5567, SOP4044 and INF1081 to applicable documents

Addition of all relevant nursing roles within the SNOD workforce to definitions

Addition of clarifying language around blood tests in relation to pregnancy in organ donors only where applicable

Addition of Jersey Human Transplantation and Anatomy Law 2018 and amended "deemed" sentence in definitions.

Policy

In England, Northern Ireland and Wales legislation requires consent is ascertained before organ or tissue donation takes place. The fundamental guiding principles of Consent in England, N. Ireland and Wales are Consent – Dignity – Quality - Honesty and Openness

The decision of the person made during their lifetime may be sufficient to provide this consent. Where no decision was expressed during lifetime, the Human Tissue Act (2004), (HT Wales Act) and **Human Transplantation and Anatomy (Jersey) Law (2018)** allows for consent to be provided by certain other people after the person has died or in the case of DCD following the decision to withdraw treatment**.** In addition, the Human Transplantation (Wales) Act 2013 allows for consent to be deemed to have been given when a person both lived and died in Wales.

Consent is the fundamental principle of this legislative framework; therefore, the Specialist Nurse-Organ Donation (SNOD) must ensure that they understand the requirements of legislation pertinent to their role.

The SNOD should approach the relative sensitively and provide enough information to check whether express consent is in place or consent is able to be deemed and where appropriate, to allow a decision regarding organ and/or tissue donation to be reached.

Purpose

The purpose of this document is to guide the SNOD through the consent conversation with the relative.

Definitions

Patient – Refers to the donor/potential donor.

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

SNOD – Refers to all Specialist Nurses Organ Donation, Specialist Requesters and Specialist Nurse Organ Donation- Family Care, with the relevant knowledge, skills and training in organ and/or tissue donation, working within NHSBT.

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

Deemed Consent - 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 where applicable within the specific country/ territory legislation.

ODR – NHS Organ Donor Register is a confidential, computerised database recording the decision of people in regard to organ/tissue donation after their death.

HCP – Medical/Nursing Healthcare Professional in the critical care area, responsible for the patient.

RIL – Relative Information Leaflets – to aid understanding of the organ and/or tissue donation process i.e. INF1164, INF1165, INF1166, INF1167.

ODT – The Organ Donation and Transplantation directorate is one of three arms of NHS Blood and Transplant (NHSBT) and provides support to transplantation services across the UK.

HT Act – Human Tissue Act, 2004.

Applicable Documents

POL164 – Consent / Authorisation for Organ and / or Tissue Donation

FRM4211– Medical and Social History Questionnaire.

INF947- Rationale document for patient Assessment Form

MPD901 – Approaching Relatives regarding Organ and Tissue Donation

FRM4281 – Consent for Solid Organ and Tissue Donation

MPD888 – NHS Organ Donor Register Account Management

SOP3817 – Access for SN-ODs and other external approved users to the NHS Organ Donor Register (ODR)

MPD394 – Management of the Deceased Donor Referral and Selection Process

INF1081 - List of NHS Hospitals with a Satellite licence Under the Extended NHSBT Research Licence (12608)

SOP5567 – Process for Consent for Removal and Storage of Organ, Tissue and Samples for Research and Other Scheduled Purposes in QUOD Licensed Hospitals Only.

SOP4044 - QUOD Consent /Authorisation and collection of samples for Quality in Organ Donation research – Specialist Nurse role.

National Institute for Health and Care Excellence (NICE): Organ donation for transplantation-Improving donor identification and consent rates for deceased organ donation
https://www.nice.org.uk/guidance/cg135

Human Tissue (Quality and Safety for Human Application) Regulations 2007
http://www.legislation.gov.uk/uksi/2007/1523/pdfs/uksi_20071523_en.pdf

The Quality and Safety of Organs Intended for Transplantation Regulations 2012
http://www.legislation.gov.uk/uksi/2012/1501/contents/made

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

NHS Blood and Transplant- Approaching the Families of Potential Organ Donors- Best Practice Guidance

SaBTO guidelines
https://www.gov.uk/government/policy-advisory-groups/advisory-committee-on-the-safety-of-blood-tissues-and-organs

INF1164 – Tissue Consent Leaflet
INF1165 – Organ Consent Leaflet
INF1166 – Eye Consent Leaflet
INF1167 – Consent Research Leaflet
DAT3301- Use of the Research Information Leaflet

Human Tissue Act 2004 - http://www.legislation.gov.uk/ukpga/2004/30/contents

Mental Capacity Act 2005 - http://www.legislation.gov.uk/ukpga/2005/9/contents

Mental Capacity Act (NI) 2016 - http://www.legislation.gov.uk/nia/2016/18/contents

Human Tissue Authority Codes of Practice http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

Codes of practice on the Human Transplantation (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

Human Transplantation and Anatomy (Jersey) Law 2018
https://www.jerseylaw.je/laws/enacted/Pages/L-27-2018.aspx

NHSBT Privacy statement for General Data Protection Regulation (GDPR): https://www.nhsbt.nhs.uk/privacy/

1. INTRODUCTION

1.1. The purpose of the comprehensive consenting process is to enable the relative involved in the consent conversation to make a fully informed decision regarding organ and/or tissue donation to ensure valid consent is ascertained.

1.2. In line with General Data Protection Regulation (GDPR) the relative's personal details must not be recorded on the consent form unless consent for organ/tissue donation is to proceed.

1.3. For consent to be lawful, sufficient information should be provided to the person involved in the consent conversation to allow a decision to be reached.

1.4. Table 1 provides the information which is considered core for the person involved in the consent conversation to be fully informed. Although there is no legal requirement to provide this information NHSBT stipulates that this core set of information **must** be provided to help ensure consent is informed.

1.5. If the person involved in the consent conversation does not wish to have in-depth information on organ and/or tissue donation to inform their decision/acceptance for organ and/or tissue donation; they must be offered relative information leaflets (RIL) or links to the NHSBT website which describe the organ and tissue donation process in further detail.

Core Information

Table 1.

Core Information

• Explain that it may be possible to donate Abdominal Organs, Cardiothoracic Organs and/ or Tissue.
 	
• Where applicable explain that the deceased may be transferred from the place of their death to a dedicated facility for tissue donation (specific regions only).
 	
• Explain that it may be possible for the organs and or tissue being considered for transplantation to be involved in a research study. (Section 5 of consent form). Specific consent for this is required
 	
• Explain that on occasion, organs/tissues that have been consented for donation may be found to be unsuitable when removed for transplant. These organs/tissues can be used in research (or other Scheduled Purposes) to improve healthcare in the future.
 	
• Explain that, where appropriate, there is also an opportunity to donate Organs/tissues/samples purely for research. Heart, lung and diabetic pancreas may be removed in a QUOD licensed hospital (please refer to **SOP5567**).
 	
• If appropriate, approach for any approved centre specific licensed studies.
 	
• N.B These purposes (referred to as **scheduled purposes** in the Human Tissue legislation) include:
  ○ Research regarding the functioning or disorders of the human body
  ○ Education and Training in relation to Human health
  ○ Clinical Audit, Quality Assurance and Performance Assessment*
* This is not a complete list of scheduled purposes rather those with which NHSBT work.
 	
Inform the relative that any remaining organ, tissue or samples following completion of testing/use for a scheduled purpose will be disposed of as per hospital/tissue establishment policy which routinely is incineration.
 	
If the person chooses not to consent to use the organs/tissue for a scheduled purpose, then any organs/tissue that have been retrieved will be disposed of as per hospital/tissue establishment policy which routinely is incineration.
 	
• **INF1167** Research Information Leaflet must be given to all relatives who Consent to Research for Scheduled purposes.
 	
• Explain that blood vessels will be retrieved and stored to support organ transplant or other surgical procedures and if not used within 14 days will be disposed of in accordance with the hospital/tissue establishment policy.
 	
• The tissue donated (including hepatocytes and heart for valves) for transplantation will be stored for extended periods in tissue establishments in preparation for transplantation
 	
• Explain that some tissue; such as blood vessels, spleen and lymph nodes will be removed and should explain that blood and tissue samples that have been obtained for screening will be subsequently biopsied, analysed and stored should future testing be necessary and stored for a period to support the management of patients post operatively.

- Explain that blood samples will be obtained from the patient for testing, including pregnancy (for organ donors only, if applicable), tissue typing, Human Immunodeficiency Virus (HIV), Hepatitis, Cytomegalovirus (CMV), Toxoplasmosis, Syphilis and Human T-lymphotropic Virus (HTLV) and that any remaining samples may be stored for future testing as necessary. *Please note: Tissue services do not currently test for CMV or Toxoplasmosis
  If travel history dictates Malaria or T-Cruzi testing, the family must be informed of this.

- **Potential paediatric donors only:** If the patient is under 18 months old or has been breast fed in the last 12 months a blood sample is required from both the mother and child and specific consent should be gained for this.

- Explain that any test results deemed to have significance for the health of a relative will be discussed in confidence with that individual.

General Data Protection Regulation (GDPR):
Inform the relatives that:

- the patient's medical records will be accessed by relevant healthcare professionals to obtain a past medical/behavioural history. This information may be passed on a need-to-know basis to other healthcare professionals in support of the donation and transplantation process. This information may also be retained by the Organ Donation Teams/Tissue Establishment.

- the information collected from them on the consent form will be stored securely and **only be** used in support of the donation and transplantation process. For further information please refer the relatives to the privacy statement on the NHSBT website: https://www.nhsbt.nhs.uk/privacy/

2. CONSENT CONVERSATION – PATIENT DEMOGRAPHICS AND POTENTIAL CORONER RESTRICTIONS FOLLOWING CONFIRMATION OF FIRST-PERSON CONSENT

2.1. The SNOD should ascertain from the relative that the patient's details including name, date of birth and address are correct.

2.2. The SNOD should ensure the patient's NHS number, where available, is written legibly on the consent form.

2.3. If the patient is to be referred to the Coroner, the relative should have already been made aware of this and it may be necessary at this point to outline any Coroner directed restrictions to donation.

3. CONSENT CONVERSATION – FIRST PERSON CONSENT

3.1. The SNOD should obtain a hard copy of the ODR registration where possible, to use as a guide for the patient's relative, when confirming the first-person consent of specific organs and/or tissues.

3.2. If the patient gave first person consent in a manner other than ODR registration, e.g. during conversation the SNOD should ask the relative if they are aware of any specific requests the patient had in relation to donating organs and/or tissue.

3.3. If the patient has provided first person consent for all organs and tissue, the SNOD should ask the patient's relative whether they require further information on the detail of organs and tissue that have been consented for. The SNOD must be guided by the relative's needs at this time.

4. NOMINATED/APPOINTED REPRESENTATIVE (POL164)

4.1 If there is a nominated /appointed representative to provide consent information the SNOD must ask what decision they are going to make on behalf of the patient. This decision will be classed as first-person consent. If they agree to organ donation the SNOD should ask the patient's relative whether they require further information on the detail of organs and tissue that have been consented for. The SNOD must be guided by the relative's needs at this time.

5. CONSENT CONVERSATION - DEEMED CONSENT (Wales and Jersey ONLY)

5.1 If consent can be deemed (as per POL164) the SNOD should approach the family in a manner whereby consent is the anticipated outcome.

5.2 The SNOD should discuss all organs /tissues that can be donated as from section 6 onwards

6. CONSENT CONVERSATION – PERSON IN HIGHEST QUALIFYING RELATIONSHIP

6.1. The SNOD should discuss all the organs and/or tissue that the patient can donate.

6.2. It may become obvious that the information being provided is in too much detail for the relative. If this is apparent, or the person has indicated that they do not wish to receive detailed information, only then should the SNOD should offer the option of consent by referring to organ and tissue groups, to accommodate the person's needs.

7. INFORMATION REQUIRED TO SUPPORT ORGAN AND TISSUE DONATION- REMOVAL OF ABDOMINAL ORGANS TO ALLOW THOROUGH INSPECTION

7.1. In order to assess the abdominal organ (s) thoroughly; in accordance with best practice guidance, the "Always Explant" approach will be adopted, carefully removing organs from the body to allow for inspection.

The SNOD can use the sentence below to explain this eventuality to the relative:

"In order to assess the abdominal organ (s) thoroughly the organs will be removed from the body to allow careful inspection. If transplantation isn't a possibility, there is an opportunity for research; to help future healthcare."

8. INFORMATION REQUIRED TO SUPPORT ORGAN AND TISSUE DONATION - TRANSFER OF THE PATIENT TO ANOTHER NHS FACILITY FOR TISSUE DONATION

8.1. The SNOD should explain to the person providing/accepting consent that in order to facilitate tissue donation, the patient's body may need to be transferred to another NHS facility for the procedure to take place.

8.2. The relative must be made aware that the patient's body may be transferred back to the hospital mortuary/funeral directors (as applicable) following the procedure and as such need to give their permission to enable the transfer to proceed.

9. CONSENTING THE PERSON PROVIDING/ACCEPTING CONSENT REGARDING THE POSSIBILITY OF RESEARCH PRIOR TO TRANSPLANTATION TO OPTIMISE ORGAN OUTCOMES

9.1. The SNOD should explain that in order to maximise transplant outcomes for recipients, both now and in the future, organs and or tissue removed for the purposes of transplantation may be involved in research prior to the organ or tissue being transplanted.

9.2. It is important to ensure that the person providing/accepting consent understands that the organs will still be transplanted and that this research will take place prior to the transplant operation and may improve transplant outcomes.

9.3. The SNOD should offer the relative further information as required or direct them to the RIL.

NOTE
If the relatives withdraw consent for all or any specific scheduled purposes at any time following the consent conversation the SNOD must inform the Hub of the exact details as soon as possible and this must be documented for the Donor records.

10. CONSENTING THE PERSON PROVIDING/ACCEPTING CONSENT TO SCHEDULED PURPOSES IN THE EVENT THAT TRANSPLANTATION IS NOT POSSIBLE

10.1. The SNOD should explain that if any donated organs or tissue cannot be transplanted, then there is the option of research for scheduled purposes for consideration: In circumstances where consent has been deemed (Wales and Jesrey only) separate consent also must be sought for research purposes.

10.1.1. That the organ or tissue could be used for a scheduled purpose.
These include:

- Research
- Education and training related to Human health
- Clinical Audit
- Quality Assurance
- Performance assessment

*All these scheduled purposes will be connected to either the functioning or disorders of the human body and interested families should be given additional information as required. Via **INF1167** Research Information leaflet

10.1.2. It is noted that this is not a complete list of Scheduled Purposes; it is however the Scheduled Purposes which NHSBT seek consent for.

OR

10.1.3. The organ and/or tissue will be disposed of as per the Human Tissue Authority (HTA) guidance. NHS Blood and Transplant's policy whilst working with other NHS Trusts is to incinerate the organ or tissue.

11. CONSENTING THE PERSON PROVIDING CONSENT TO SCHEDULED PURPOSES FOR OTHER ORGANS AND/OR TISSUE NOT BEING CONSIDERED OR NOT ACCEPTED FOR TRANSPLANTATION.

11.1. If the person is providing consent to organs and/or tissue for scheduled purposes, the SNOD should offer the option of donating other organs or tissue not being considered for transplantation for use in research.

11.2. As required for a centre license specific study the SNOD should offer further information about the type of research either verbally and by providing a RIL.

Note

In England, Wales and Northern Ireland, the removal of organs for scheduled purposes (consent form section 3a) must only proceed in hospitals covered by a satellite licence under NHSBT's extended HTA Research Licence 12608. The SNOD must check INF1081 to ascertain this information.

Paediatric donors (less than 18 years) are excluded from removal of organs for research under consent form section 3a.

11.3. In England, Wales and Northern Ireland, the removal of organs for scheduled purposes (consent form section 3a) can now be considered. It must only proceed in hospitals covered by a satellite licence under NHSBT's extended HTA Research Licence 12608. The SNOD/SR must check **INF1081** to ascertain this information.
Removal of hearts, lungs and diabetic pancreases are permitted under **SOP5567**.

11.4. Approach the family for removal of heart, lungs and diabetic pancreas (if applicable) for scheduled purposes if they are:

- Contraindicated for donation.
- Offered and declined by all centres for transplant/clinical use. i.e. whole heart for valves/ tissue.

The SNOD can use the sentences below to explain this eventuality to the relative

"NHSBT supports the removal of organs for scheduled purposes, to improve and advance healthcare including transplantation. This will help develop new treatments in the UK and worldwide.
Donated organs are treated with the utmost respect by the researchers.
With your consent, we will approach researchers and tissue/bio banks who wish to receive these organs for their studies. Organs will only be removed if they are accepted for a research study.
We won't be able to remove organs if we don't proceed to theatre.
There are occasions where we are unable to remove organs for research due to logistical reasons.
We will update you of the outcome of the organs you have consented for removal for research, either via a telephone call or in the donation outcome letter."

11.5. The SNOD should explain to the person involved in the consent conversation that post research any remaining organ, tissue or samples with generic consent, may be stored for future research or may be disposed of as per local hospital/tissue establishment policy.

11.6. Consent for the use of specific organs or tissue in research that are not being considered for transplantation will need to be provided by the person providing consent and documented on **FRM4281** Consent – Solid Organ and Tissue Donation form.

12. USE OF THE RESEARCH LEAFLET: WHAT'S INVOLVED - ANIMAL, DNA OR COMMERCIALTESTING

12.1. The SNOD **must** inform the relative (s) that research studies may involve animal, DNA or commercial testing. In addition, the research leaflet **INF1167** must be given to the relative (s) agreeing to the donation of organ / tissue donation, allowing them time to read the information. A suggested sentence to introduce the leaflet is:

"There is another opportunity to help in the development of medicine by donating organs to research. Here is a leaflet with more details about what research involves. For your information, a small amount of studies may involve DNA or animal testing or can be commercial in nature. Please read this leaflet and ask me any questions you may have".

12.2. NHSBT support this **proportionate** approach by providing an information leaflet and allowing the Specialist Nurse Organ Donation to put this into context for the relatives when required. **DAT3301** contains further information about animal, DNA or commercial testing.

13. HUB OPERATIONS AND TRACEABILITY

13.1. You must verbally communicate with Hub Operations if donor relatives request any restrictions after reading **INF1167** / talking to Specialist Nurse Organ Donation.

13.2. Consent / authorisation can be withdrawn up to the point of use in research project.

13.3. Relatives can say no to animal, DNA or commercial testing and can still donate organs / tissue for research in other studies.

13.4. Hub Operations have information about which category the research study falls into - DNA analysis etc - based on a tick box of info provided by the researchers themselves.

13.5. The Specialist Nurse Organ Donation must inform Hub Operations about any restrictions placed on research from relatives.

13.6. Any restrictions should be documented on section 5 of the consent / authorisation form.

13.7. Any QUOD research restrictions should also be documented on the QUOD worksheet.

14. SNOD/NP CONTACT DETAILS

14.1. The SNOD must ensure that they offer their name and contact number to the relative.