



Human Tissue Authority

Code of Practice on the Human
Transplantation (Wales) Act 2013

May 2014 (updated July 2017)

Note

This document must not to be used operationally until 1 December 2015 when deemed consent becomes operational in Wales.

If you have any questions please contact the Human Tissue Authority on enquiries@hta.gov.uk.

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Introduction

This section provides an introduction to the Code of Practice and relevant background information.

Purpose of this Code of Practice

1. This Code of Practice provides practical advice and guidance on the Human Transplantation (Wales) Act 2013.
2. This Code of Practice is primarily intended for use by Specialist Nurses for Organ Donation (SNODs), other clinicians and professionals working in the transplantation sector in Wales. It may also be of assistance to clinicians in other areas and specialities, as well as the public.
3. SNODs are employees of NHS Blood and Transplant (NHSBT) and when they are required to make a difficult decision, or encounter a novel situation, there are decision-making processes in place to support them. This means that SNODs are always able to discuss the situation with colleagues and if necessary contact a member of the senior management team to make the final decision. This ensures consistency of approach and high-quality decision making.
4. Deemed consent becomes operational in Wales on 1 December 2015.

Authority under which this Code of Practice is produced

5. This Code of Practice is produced under section 26 of the Human Tissue Act 2004, as amended by section 15 of the Human Transplantation (Wales) Act.

The role of the Human Tissue Authority

6. The Human Tissue Authority (HTA) is the statutory regulator which supports public confidence by licensing organisations that store, use and remove human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. We also assess and make decisions on organ and bone marrow donations from living people.
7. In Wales, the HTA will continue to license establishments under the following legislation:
 - Human Tissue Act 2004;
 - Human Tissue (Quality and Safety for Human Application) Regulations 2007;
 - The Quality and Safety of Organs Intended for Transplantation Regulations 2012.
8. As a regulatory body, the HTA does not have a role in making government policy. The HTA is required to provide advice and guidance to the legislatures in England, Wales and Northern Ireland on issues within its remit, including transplantation.

Overview

9. The Human Transplantation (Wales) Act allows for consent to deceased organ 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 under the age of 18 (child)
 - b) An adult who has lived in Wales for less than twelve months
 - c) An adult who has lived in Wales for more than twelve 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 (more information on capacity decisions can be found at [paragraphs 62 to 74](#)).
10. 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.
11. 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, unless a person with a close relationship provides evidence that the person did not want to be an organ donor.
12. In cases where there must be express consent this can mean the decision of the person in life, the decision of an appointed representative/s, the decision of a person in a qualifying relationship or the decision of a person with parental responsibility in the case of children.
13. If a person made a decision in regard to organ donation when they were alive, their consent cannot be deemed.
14. If a person appointed a representative/s to make a decision, their consent cannot be deemed. The decision of the appointed representative/s should be acted upon. If the appointed representative is unable to act, then the express consent of a person in a qualifying relationship or a person with parental responsibility (in the case of children) may be sought.
15. The Human Transplantation (Wales) Act is permissive in the sense that it allows consent to organ donation to be deemed in certain circumstances. However, it does not mandate that organ donation goes ahead in such cases.
16. On occasion a person will die and there will not be any family or friends in existence or available for the SNOD to speak with. Although it is unlikely, it may be possible to establish that the person both lived and died in Wales and was ordinarily resident there, that they were an adult and they had not lacked capacity for a significant period prior to their death. In this circumstance it would be lawful for the person's consent to organ donation to be deemed, if there was no other recorded wish.
17. However, the Quality and Safety of Organs Intended for Transplantation Regulations 2012 require a minimum set of information to be collected before a

transplant goes ahead. Much of this information would normally be collected from family and friends of the deceased person. Where it is not possible to collect the minimum set of information the Regulations only enable a transplant to go ahead following a risk assessment, clearly documented, which demonstrates that the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.

18. The Human Transplantation (Wales) Act does not make any material amendments to the regulatory framework for living organ donation.
19. In England and Northern Ireland the Human Tissue Act governs consent to organ donation. In both nations it is unlawful to deem consent for organ donation. The same is true in Scotland, where the governing legislation on authorisation is the Human Tissue (Scotland) Act 2006.

How to record a decision about organ donation

20. The Human Transplantation (Wales) Act does not require that a person records their decision about organ donation in a specific manner.
21. This means that it is for the individual to decide how they do this, and options include telling a friend or family member, and registering on the Organ Donor Register (ODR).
22. However, the only way to be certain a decision will be accessible by a SNOD is for it to be recorded on the ODR. The ODR is checked in every potential case of organ donation after death and the information on it will be communicated by the SNOD to family and/or friends.
23. Prior to deemed consent becoming operational on 1 December 2015 a new ODR will be launched which will allow the following decisions to be recorded:
 - a) I consent to donate all my organs after death;
 - b) I consent to donate some (specified) organs after death;
 - c) I do not consent to donate my organs after death;
 - d) I wish to appoint a representative to make a decision on organ donation after death on my behalf.
24. People across the whole of the UK will be able to record a decision, selecting one of the options at paragraph 23 above.

Practical advice and guidance

This section provides advice and guidance on the operational aspects of deemed consent in Wales.

Deemed consent and express consent

25. In Wales, in the absence of express consent, transplantation activities are lawful if carried out with deemed consent unless one of the categories at points a to d (below) applies.

Children

- a) A person under 18 years old;

Excepted Adults

- b) An adult who had lived in Wales for less than twelve months at the time of their death
- c) An adult who had lived in Wales for twelve months or more, but were not ordinarily resident in Wales ([paragraphs 53 to 61](#))
- d) An adult who lacked mental capacity to understand the notion of deemed consent for a significant period before their death ([paragraphs 62 to 74](#)).
26. When a person is not within one of the categories above, it is lawful for their consent to organ donation to be deemed, unless:
- a) They made a decision in life in regard to organ donation;
- b) They appointed a representative/s to make a decision on organ donation on their behalf;
- c) A relative or friend of long standing objects on the basis that the deceased person did not wish to be an organ donor;
- d) The transplantation activity involves excluded relevant material, specified by Welsh Ministers in Regulations.
27. If an adult or child had not made a decision before death, the SNOD should seek to establish whether they appointed a representative/s. Checking the ODR and asking the family/friends present, or who are contactable, if they are aware of any appointed representative/s or believe there is a person who may know if there is an appointed representative/s, are reasonable and sufficient steps to take.
28. If, following these checks the SNOD does not have any reason to believe that there is an appointed representative/s, they should record this in the person's medical record or other appropriate document. If there is not an appointed representative/s, for people who are excepted adults or a child, the SNOD should seek consent from a person in a qualifying relationship in accordance with the ranking set out in [paragraph 110](#) or a person with parental responsibility in the case of a child.
29. To appoint a representative under section 8 of the Human Transplantation (Wales) Act there are specific requirements ([see paragraphs 86 to 102](#)), and this role is not the same as someone who has a Lasting Power of Attorney relating to personal welfare or has been nominated to act under other legislation.

Establishing whether deemed consent applies

Children

30. In the majority of cases the SNOD will be able to establish easily the age of the person.
31. If the person is under the age of 18 it is unlawful for their consent to be deemed.
32. Deemed consent may apply to a person from 00.00 on the day of their eighteenth birthday.
33. It is recommended that medical records are checked to confirm the date of birth. If there is uncertainty as to whether the date of birth is accurate, for example the deceased person may have been born outside the UK and not issued with a birth certificate, then a conversation should take place with family/friends to establish the person's age. This conversation does not have to be face-to-face, and could be conducted by phone, email, video conferencing, video calling or any other method as practical. A note of the conversation should be made in the person's medical record or other appropriate document.
34. If it is not possible to establish that the person is over the age of 18, then the express consent process should be followed.
35. Organ donation remains a possibility for a child who dies in Wales provided there is express consent to organ donation. Consent to organ donation given by a child during his or her lifetime will constitute express consent, if at the time of the decision to give consent the child was competent to make this decision (provided such consent was not subsequently withdrawn).
36. When assessing whether a child was competent to make a decision to consent to organ donation, for a child aged under the age of 16, the test is whether it would appear to a reasonable person that the child had sufficient understanding and intelligence to enable them to understand fully what was proposed. This test is an objective one, and involves weighing up the information available on the intelligence and understanding of the child. This might involve collecting evidence from family and friends regarding the child's level of understanding at the time he or she made a decision in relation to organ donation. For children aged 16 to 17, the starting assumption must be that the child has the capacity to make a decision unless it can be established that they lack capacity, in accordance with the Mental Capacity Act 2005.

37. The table below is taken from section 6 of the Human Transplantation (Wales) Act and provides a useful summary of the meaning of express consent in every case that may involve children:

Table One – Express Consent (Children)	
Case	Meaning of express consent
1. The child is alive and case 2 does not apply.	The child's consent.
2. The child is alive, no decision of the child to consent, or not to consent, to the activity is in force, and either the child is not competent to deal with the issue of consent or is competent to deal with the issue but fails to do so.	Consent of a person who has parental responsibility for the child.
3. The child has died and a decision of the child to consent, or not to consent, to the activity was in force immediately before death.	The child's consent.
4. The child has died, case 3 does not apply, the child had appointed a person or persons to deal with the issue of consent in relation to the activity and someone is able to consent under the appointment.	Consent given by a person or persons appointed.
5. The child has died, case 3 does not apply and the child had appointed a person or persons to deal with the issue of consent in relation to the activity, but no one is able to give consent under the appointment.	Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person in a qualifying relationship to the child at that time.

<p>6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.</p>	<p>Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person in a qualifying relationship to the child at that time.</p>
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38. If there is no-one alive who had parental responsibility for the child immediately before they died, consent can be sought from a person who had a qualifying relationship with the child at the time they died in accordance with the ranking set out at [paragraph 110](#).
39. Where the express consent of a person with parental responsibility is required and they state they will not consent to organ donation, it is not possible to seek consent from someone in a qualifying relationship.
40. If there is more than one person with parental responsibility, and they cannot come to agreement on whether donation should go ahead, it is lawful for donation to proceed with the consent of just one person with parental responsibility. However, it is recommended that the SNOD seeks to support those with parental responsibility to reach a consensus.
41. Donation does not have to go ahead, even if there is the consent of a person with parental responsibility. The SNOD should consider the needs of all the people with parental responsibility.
42. When the child is 16 or 17 years old and married, then it remains the case that consent should be sought from a person with parental responsibility, unless the child had made a decision or appointed a representative. If there is no-one with parental responsibility, then consent should be sought from the person highest up the qualifying list, which is likely to be their spouse.
43. Where a Local Authority has parental responsibility for the child, it is suggested that those who are in the zone of parental control and who have a close relationship to the child are involved in reaching a decision on organ donation. Local authorities should consider appropriate arrangements to enable decision-making in relation to organ donation.

Excepted Adults

What is meant by “in Wales”?

44. For the purposes of the Human Transplantation (Wales) Act “in Wales” means within a Welsh local authority area. Information on the local authorities can be found on the Welsh Local Government Association [website](#).
45. In most cases the SNOD will be able to establish whether a person lived (and died) in Wales, either from medical records or through discussions with the family/friends.
46. If there is doubt, the SNOD should check whether the deceased person’s address was in Wales. If this is not possible, for example the service is unavailable for a period of time which would mean the opportunity for donation is missed, and the person cannot safely be assumed to be resident in Wales, then the express consent process should be followed.

Residency

47. In the majority of cases a SNOD will be able to establish where the deceased person lived, and whether they were ordinarily resident (see paragraphs 53 to 61) at an address in Wales.
48. For deemed consent to apply, the deceased person must have lived in Wales for twelve calendar months prior to their death. For the purposes of deemed consent the time of death is taken to be the date on which death is confirmed by one of the processes laid out in the AoMRC Code of Practice for the Diagnosis and Confirmation of Death.

Example

An adult dies in a Welsh hospital on 15 February. It is established by speaking to their family/friends that they moved to Wales on 16 February of the previous year. Deemed consent does not apply to them, as they had not lived in Wales for twelve calendar months when they died.

Had the person’s friends/family confirmed that they had moved to Wales on 15 February, and that the person was ordinarily resident in Wales, deemed consent would apply to them, as they had lived in Wales for twelve calendar months when they died.

49. The twelve-month period test does not involve counting the number of days a

person had lived in Wales. Rather, it is necessary to establish that a person had lived in Wales for twelve calendar months.

50. In some cases, it may not be possible to establish the exact date a person started living in Wales. For example, their family/friends may not be able to remember exactly when they moved to Wales, but do know it was within the last ten to fourteen months.
51. When this is the case and there is no documentary evidence available to confirm the time spent at the address, then deemed consent should not apply and the express consent process should be followed.
52. If there is documentary evidence, but this cannot be accessed within a timeframe which would allow donation to go ahead, for example it is 8pm and the office where the information is held does not reopen until 9am the following day, then deemed consent should not apply and the express consent process should be followed.

Ordinarily Resident

53. The test for ordinarily resident attaches a number of qualities to a person's residency, in order for them to be considered ordinarily resident. These qualities are:
 - a) The residence was adopted voluntarily.
The fact that the person chose to come to Wales at the request of an employer rather than seek another job does not necessarily make their presence in Wales involuntary, for example. The SNOD will need to ask questions to gather evidence in such circumstance and make a decision on whether the person's residence had a voluntary quality to it.
 - b) The person was resident for settled purposes.
This might be for only a limited period, but has enough continuity to be properly described as settled. Business, employment and family can all provide a settled purpose, but this list is not exhaustive.
 - c) The person's residency in Wales supported the regular order of their life for the time being.
The person may have had temporary absences from Wales and still be considered ordinarily resident. The SNOD will need ask questions to gather evidence in such circumstance and make a decision on whether the person's residence supported the order of their life.
54. These qualities must be assessed on a case-by-case basis, and whether the qualities have been satisfied will primarily be a question of fact and degree. In

many cases the SNOD will be able to establish easily whether the person's residence was characterised by the qualities above. When it is not initially clear that this is the case, it is recommended that there is a discussion with family/friends to gain more information about how the person would have characterised their residency in Wales.

55. The ordinarily resident test involves weighing up information, and when a SNOD is in doubt about whether the person would have been ordinarily resident, the express consent process should be followed.

Example

A person may work in Cardiff and live there four nights a week, and spend the other three nights at their family home in Bristol. The SNOD should ask questions of the family/friends to establish how the person would have identified their residency. The SNOD may wish to ask where the person would have referred to as home. It will then be for the SNOD to weigh up the evidence to establish whether or not the person was ordinarily resident in Wales.

The SNOD will need to consider whether the person's residence in Wales was:

- a) Voluntary; and
- b) For a settled purpose; and
- c) Supported the regular order of their life for the time being.

Students

56. Education can have the quality of a settled purpose and a student may be regarded as a person ordinarily resident in a particular place. It will be for discussion with the person's family/friends to determine whether the student's residence in Wales had the necessary qualities described above before deciding whether deemed consent applies.

Prisoners

57. A person who is in prison cannot be stated to be residing in Wales through choice, and cannot be considered ordinarily resident in Wales during their time in prison. This includes prisoners who normally live in Wales and who are in prison in Wales. People in prison cannot have their consent to organ donation deemed.

Armed Forces

58. People serving in the armed forces who are directed to live in Wales (i.e. who are posted to Wales) cannot be considered to be ordinarily resident in Wales because they will not be living in Wales voluntarily. They cannot therefore be deemed to have given consent to organ donation
59. The families of armed forces personnel who have been posted to Wales and who decide to join them for the duration of their posting may in certain circumstances, as established by case law, be considered to be ordinarily resident in Wales. Therefore, the SNOD will need to ask questions in order to establish whether such family members would have been considered ordinarily resident, on a case-by-case basis.
60. Those people serving in the armed forces, who are not directed to live in Wales, but do so out of choice, can have their consent to organ donation deemed to have been given, if they are neither a child nor an excepted adult.

Other groups

61. There are other groups of people, for example those detained under mental health legislation and diplomatic staff who may or may not reside in Wales voluntarily. It will be for the SNOD to ask questions of family/friends to establish whether the residence was voluntary, and this will need to be done on a case-by-case basis.

Mental capacity

62. Deemed consent does not apply to people who for a significant period before dying lacked the capacity to understand the notion that consent to transplantation activities can be deemed to be given.
63. If a person did lack capacity to understand that consent can be deemed for a significant period before their death, then the express consent process should be followed.
64. If at the point at which a person lost capacity deemed consent did not apply to them, for example, they were a child or did not live in Wales, then their consent cannot be deemed.
65. In some cases it will be evident that a person lacked capacity for a significant period before dying as they may, for example, have been in a coma for a period of years.
66. When it is not evident, but there is a possibility, in order to establish whether a

person lacked capacity for a significant period before their death, the SNOD should take the following steps:

- a) Check the medical records of the person to establish whether there was any history of conditions or illness which may have impacted on the person's capacity to understand the notion of consent being deemed or any assessment of the person's capacity to understand the notion of consent being deemed. It is important to note that a record of an episode or episodes of such an illness would not necessarily mean that a person would not have been able to understand the notion. However, it should prompt further investigation by the SNOD.
- b) If there is no indication in the medical records of a condition or illness which may have impacted the person's capacity to understand deemed consent or any assessment of the person's capacity to understand the notion of consent being deemed, then the SNOD should make a note of this.
- c) If there is an indication in the medical records of a condition or illness that may have impacted on the person's capacity to understand deemed consent, the SNOD should undertake further investigations which address the specific circumstances of the person's condition or illness. The issue of mental capacity should be raised by the SNOD when speaking to the friends/family to inform them that consent will be deemed, in order to check that the person did have capacity. It is envisaged that this would take the form of a simple question, for example, "Do you think that your relative/friend would have understood that consent to organ donation could be deemed?"

Example

If the person had been in hospital for some time it may be appropriate to speak to a member of the team caring for them to establish their level of understanding of medical and consent issues generally.

- d) Where there is evidence of an illness that may have impacted the person's capacity to understand deemed consent, in most cases it will be the family/friends who are able to provide the SNOD with the most accurate information as to whether they understood consent to organ donation could be deemed. The SNOD should ask the family/friends whether they believe the person had a level of capacity to understand deemed consent, or

analogous notions. This may be a detailed discussion, and if at the end of this the SNOD is not satisfied on the balance of probabilities (that is, that it is more likely than not), that the person could have understood the notion of deemed consent, then the express consent process should be followed.

Significant period

67. The Human Transplantation (Wales) Act requires a person to have lacked capacity to understand the notion of deemed consent for a significant period before dying, to be a person excepted from deemed consent.
68. The exact duration that a person lacked capacity is not specified in the Human Transplantation (Wales) Act, but the period must be significant and this means a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given. The significant period test is, therefore, an objective test in the sense that it must be based on the circumstances of each case and the facts presented. The significant period only negates deemed consent; if the person had made a decision to consent, or not to consent, then that express consent remains in force regardless of a subsequent loss of capacity.
69. In practice, a significant period should mean that the person did not have capacity to understand the notion of deemed consent for a period of at least twelve months before their death. The person's family, friends or carers should consider the significant period to be a period, which is long enough that the person's decision not to register a decision in regard to organ donation could not be said to be a conscious decision.
70. The twelve-month period is provided in this first Code of Practice on the Human Transplantation (Wales) Act in order to provide regulatory certainty to SNODs and other practitioners.
71. In future this Code of Practice will be reviewed and consideration given as to the continued need for the twelve month period.
72. A person may have chosen when they had capacity in regard to organ donation, to appoint a representative/s to act on their behalf under section 8 of the Human Transplantation (Wales) Act. When this is the case, the consent of the appointed representative is required and the guidance at [paragraphs 86 to 101](#) should be followed.
73. A person may have made an advance statement in regard to organ donation prior to losing capacity or have appointed a person with Lasting Power of Attorney on health and welfare to make decisions in regard to organ donation. If this is the

case, then the decision recorded in the advance statement or the decision communicated by the Lasting Power of Attorney is express consent or refusal.

74. The table below is taken from section 5 of the Human Transplantation (Wales) Act and provides a useful summary of the meaning of express consent in every case that may involve excepted adults:

Table Two – Express Consent (Adults)	
Case	Meaning of express consent
1. A decision of the excepted adult to consent, or not to consent, to the activity was in force immediately before death.	The excepted adult's consent.
2. Case 1 does not apply, the excepted adult had appointed a person or persons to deal with the issue of consent in relation to the activity and someone is able to consent under the appointment.	Consent given by the person or persons appointed.
3. Case 1 does not apply and the excepted adult had appointed a person or persons to deal with the issue of consent in relation to the activity, but no one is able to give consent under the appointment.	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.
4. None of cases 1, 2 or 3 applies in relation to the excepted adult.	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.

Establishing whether a person made a decision during life

75. The Human Transplantation (Wales) Act provides that when a person had made a decision during life to either consent to, or not consent to, organ donation, that decision overrides the issue of deemed consent.
76. This means that if a person had made a decision to donate their organs then this decision establishes their consent and their consent must not be deemed.
77. If a person had made a decision not to donate their organs then this decision establishes that they have not given their consent. It would be unlawful to deem the person's consent.
78. When a person had neither made a decision about organ donation nor appointed a representative/s, then their consent may be deemed, unless they are a child or an excepted adult, [paragraphs 30 to 74](#). Family and friends must be given the opportunity to produce evidence that the person did not wish to be a donor (if that is the case) and the SNOD should ask those present or contactable whether the person had stated they did not wish to be a donor.
79. The Human Transplantation (Wales) Act does not specify where a person should record their wishes in regard to organ donation. Therefore, the SNOD should take reasonable steps to ensure they have made appropriate checks to establish whether a person had made a decision during life, [paragraphs 75 to 101](#).
80. If there is more than one recorded decision of the person, and these are contradictory, it is the most recent decision that should be observed.

Example

A SNOD checks the ODR for the decision of a person whose life sustaining treatment is to be withdrawn on 2 November of a given year. There is a decision to consent to the donation of all organs which was recorded on the ODR on 25 January of that year. When the SNOD speaks to the family, the person's wife produces a letter dated 3 March of the same year which explains that his decision was not to donate his organs. In this case it is the decision within the letter which should be observed as this was made closer to the date of death.

81. The HTA considers the steps at [paragraphs 82 to 101](#) are the minimum to be

taken by the SNOD when seeking to establish whether a person had made a decision on organ donation in life.

Organ Donor Register

82. The ODR should be checked to establish whether the person had registered either a decision to, or not to, donate their organs. If there is a recorded decision or details of an appointed representative/s the SNOD should share this information with the family.
83. If the recorded decision was to donate some or all organs, and the family state that the person had changed their minds and did not wish to donate their organs, they should be asked what evidence they have to show this is the case (see [paragraphs 124 to 134](#)).
84. If the recorded decision was not to be an organ donor then this can be communicated to the family. If the family state that the person had changed their mind and wanted to donate their organs, they must provide the SNOD with the evidence they believe proves the person did make a decision to be an organ donor and that this decision supersedes their recorded decision not to donate.
85. If the SNOD accepts that the person has changed their mind, having previously recorded a decision not to consent on the ODR, then donation could go ahead.

Appointed representatives

86. If there is no decision recorded on the ODR, then the SNOD should make checks to establish whether the person appointed a representative/s to make a decision on their behalf in regard to organ donation.
87. Under the Human Transplantation (Wales) Act a child can appoint a representative to make a decision on their behalf.
88. The name and contact details of the appointed representative/s may have been recorded on the ODR, and this is the first check the SNOD should make. It is likely this will take place when the ODR check is being made as per paragraph 82. If there is a recorded appointed representative/s, the SNOD should contact them and ask them to make a decision on behalf of the person.
89. It is possible that the person made the appointment in regard to one or more of the transplantation activities.
90. If the appointed representative on the ODR cannot be contacted in time to make a decision, or is unwilling to make a decision, then a person in a qualifying relationship may be approached to make a decision about organ donation, or a person with parental responsibility in the case of a child. The list of qualifying relations will be ranked in accordance with [paragraph 110](#).
91. If the details of the appointed representative are on the ODR, the SNOD does not need to carry out the checks below at [paragraphs 92 to 101](#).
92. If there is no record of an appointed representative/s on the ODR, the SNOD should ask the family/friends of the person if they are aware of a person/s who were appointed representative/s to make decisions on organ donation.
93. If the SNOD is informed that there is an appointed representative/s, the checks at paragraphs 94 to 101 below should be undertaken to ensure they have authority under the Human Transplantation (Wales) Act.
94. If the appointment was made orally the SNOD needs to check that the appointment was witnessed by at least two people. This can be confirmed either by the two witnesses or in a document produced with the two people's signatures confirming they witnessed the appointment.

95. If the appointment was made in writing, the SNOD should be assured that one of the statements at a to c below is true:
- a) The document making the appointment was signed by the person in the presence of a witness who confirmed the signature; or
 - b) It was signed by another person at the direction of and in the presence of the person, and in the presence of a witness who confirmed the signature; or
 - c) It was contained in the will of the person, and that will was made lawfully.
96. If more than one person has been appointed, unless the appointment provides that they are appointed to act only jointly, the default position is that the appointed representatives can make the decision jointly and separately. This means that the representatives do not have to agree, so one of them can give consent regardless of what the other representative/s decide.
97. However, where the appointment provides that multiple representatives must act jointly. This means that all representatives must agree before consent can be established. In these circumstances, if one representative cannot be contacted then the other representatives cannot give consent.
98. It may be the case that a person appointed representative/s but did not record them on the ODR or tell their family/friends about them. It is recognised that it is not practical for the SNOD to make numerous checks to establish whether a person appointed a representative/s. It is therefore considered adequate for a SNOD to check the ODR and to ask family/friends. It is important that a note is made of these checks and any discussions with family/friends.
99. A child cannot act as an appointed representative.
100. Regulations will be made by Welsh Ministers describing other persons who may not act as an appointed representative. [Guidance on the Regulations will be drafted by the HTA in due course and made available on the HTA website.](#)
101. If a person had nominated a representative/s under section 4 of the Human Tissue Act, they are considered an appointed person or persons for the purposes of the Human Transplantation (Wales) Act. A child cannot nominate a representative under the Human Tissue Act.

When there is no recorded decision or appointed representative(s)

102. Once the SNOD has established that the person had not recorded a decision on the ODR or appointed a representative/s, they should ask the family/friends present or contactable whether they are aware of the person's decision in regard to organ donation after death.
103. If the SNOD is informed that the person had recorded their decision in writing, but not on the ODR, the SNOD should seek to establish where that record is held and to gain a copy of it.
104. If the SNOD is informed that the person recorded their decision orally, the SNOD should speak with the person who was informed of the decision and make a note of the details of this conversation.
105. The SNOD will need to make a decision, based on the evidence presented to them, whether they are satisfied that this constitutes the person's decision in life. It is considered that written, signed and dated evidence which was witnessed is most likely to satisfy the SNOD that this was the decision of the person in life.
106. This does not mean that other forms of evidence, such as oral evidence, will not satisfy a reasonable person, but rather that the SNOD must make a judgment as to whether it is reliable.
107. If the SNOD is not satisfied that the evidence presented to them constitutes a decision of the person in life, then the person's consent can be deemed (unless they are a child or an excepted adult).
108. If the SNOD is informed by family/friends that the person had not made a decision in life, then their consent to organ donation may be deemed (unless they are a child or an excepted adult).
109. There is no requirement that organ donation goes ahead when consent can be deemed, but rather it would be lawful for such organ donation to take place.

The role of family and friends

110. The Human Transplantation (Wales) Act includes at section 19(3), and the Human Tissue Act at section 27(4), a list of qualifying relationships:
- a) Spouse, civil partner, or partner;
 - b) Parent or child;
 - c) Brother or sister;
 - d) Grandparent or grandchild;
 - e) Child of a brother or sister (niece or nephew);
 - f) Stepfather or stepmother;
 - g) Half-brother or half-sister; or
 - h) Friend of long standing.
111. A person is another person's partner if the two of them lived as partners in an enduring family relationship. Partner can be different genders or be of the same gender.
112. A friend of long standing is not defined in the legislation as having a specified time period attached to the friendship. Whether someone is a friend of long standing will be a question of fact and degree in each case and the SNOD may ask questions and/or request evidence as necessary to establish what degree of friendship existed.
113. When the person is an excepted adult (see [paragraphs 44 to 74](#)), and they did not make a decision in life or appoint a representative/s, then the list will be ranked in accordance with paragraph 110.
114. When the person is a child, and they did not make a decision in life or appoint a representative/s, and there was no-one with parental responsibility for them immediately before they died, then the list will be ranked in accordance with paragraph 110.
115. When there is disagreement between people in different positions on the ranked list, it is recommended that the SNOD seeks to provide those people with the time and information they need to come to an agreement.
116. If those close to the person object to the donation, for whatever purpose, when the person (or their appointed representative, see [paragraphs 86 to 101](#)) has explicitly given their consent, or their consent can be deemed, the SNOD should seek to discuss the matter sensitively with them. They should be encouraged to accept the

person's wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes.

117. In a situation in which the list is ranked and agreement cannot be reached between people of the same rank; it is lawful to proceed with the consent of just one of those people. This does not mean that the consent of one person must be acted on, and the SNOD may make the decision not to proceed due to the emotional impact this would have on family and friends.

Circumstances in which the qualifying list does not apply

118. For the purpose of providing evidence that the person did not want to be a donor in circumstances where consent can be deemed, this evidence can be provided by any relative or a friend of long standing. The relative does not have to be one of those listed above at [paragraph 110](#), for example it may be a cousin, aunt or uncle who provides such information.
119. As the list does not apply in situations where evidence is presented that the person would not have wanted to be an organ donor, there is no ranking of relationships. This means that it is the quality of the evidence that should be taken into consideration by the SNOD, and not the relationship of the person presenting it to the deceased.

Table Three – Does the ranked qualifying list apply?		
	Ranked qualifying relationship list applies	Ranked qualifying relationship list does not apply
The person is an excepted an adult who did not make a decision in life or appoint a representative	✓	
The person is a child who did not make a decision in life or appoint a representative, and there in no-one with parental responsibility	✓	
A person is presenting evidence a deceased person, for whom consent could be deemed, did not want to be an organ donor		✓

More information on family and friends

120. Family and friends may be asked to provide medical and social background information on the person in order that a risk assessment can be carried out. This is not part of the consent process, but rather allows for clinical decisions to be made about organ donation in light of all the relevant information.
121. It should be noted that there is no requirement that organ donation goes ahead when there is express consent or consent can be deemed, but rather it would be lawful for organ donation to take place. It will be a decision for the SNOD as to whether to proceed to donation when deemed consent is in place, but the family/friends object.
122. On occasion, a person will die and there will not be any family/friends who can be identified. When this is the case, please see [paragraph 16](#) for information.
123. If there is no registered decision, and the person did not appoint a representative(s), please refer to [paragraphs 16 and 17](#) for further information.

Evidence which would satisfy a reasonable person that the person did not want to be an organ donor

124. If a person is not a child or an excepted adult, and they had not made a decision in life or appointed a representative/s, then their consent to organ donation may be deemed.
125. When this is the case the SNOD should inform those people present or contactable that consent may be deemed unless the family or friends object, based on what they know of the wishes of the person.
126. If the SNOD is informed by relatives or friends that the person did not want to be an organ donor, they should make reasonable enquiries as to why the relatives or friend thought that to be the case. In terms of who can provide the information that the person would have objected, the Human Transplantation (Wales) Act provides for a relative or a friend of long standing to be able to do so.
127. When information is provided by a relative or friend of long standing that the person did not want to be an organ donor, this must satisfy a reasonable person that the person would not have given consent.
128. In order to satisfy the reasonable person test, the SNOD should ask that they are presented with all the evidence to support the assertion that the person did not want to be an organ donor.
129. When there is written evidence and this is signed by a witness, this would form the express consent of the deceased and so consent must not be deemed.
130. When there is written evidence and this has not been witnessed, it will be for the SNOD to make the decision whether this is evidence that would satisfy a reasonable person.
131. Where there is oral evidence, it will be for the SNOD to make the decision whether this is evidence that would satisfy a reasonable person.
132. The reasonable person test is an objective one, and involves the person making the assessment (in this case the SNOD), deciding how much weight the evidence has.
133. In order to assess the weight of the evidence presented, the following questions may be considered to aid the SNOD in reaching a decision:

- a) Is the evidence presented as reflecting the views of the person, or the views of the family/friends presenting it? The test requires that evidence must be presented of the person's view. Therefore, more weight should be given to evidence which is presented as being a reflection of the person's view.
- b) Is the evidence in writing, signed and dated by the person and witnessed? If this is the case, then this is likely to form an express decision of the person.
- c) Is the evidence oral? If so, is it corroborated by more than one person? It is more likely to pass the reasonable person test if more than one person is able to confirm that the person orally stated that they would not have given their consent to donation.
- d) How recent is the evidence? The Human Transplantation (Wales) Act requires the most recent evidence to be relied on, therefore the SNOD should establish when the record was made or the conversation took place and note this in the person's medical record or other appropriate document.
- e) How well does the person providing the evidence know the person? It is not necessarily always the case that a person knows someone well simply because they are related. For example, a person may have had a carer who is not related to them, but spends every day with them.

134. Stating that the person was not aware that deemed consent affected them is not sufficient evidence, on its own, that a person did not want to be an organ donor.

Novel transplants

135. The Human Transplantation (Wales) Act makes provision at section 7(2) for Welsh Ministers to make Regulations setting out which organs will not be included in the deemed consent system, these are referred to as “excluded relevant material” . [A list of such organs and tissues will be published on the HTA website](#), and this will be updated when changes are made to the list.
136. If an organ is on this list, then express consent must be in place for removal, storage or use for the purpose of transplantation to be lawful.
137. The tables below are taken from section 7 of the Human Transplantation (Wales) Act and provide a useful summary of the meaning of express consent in every case (adults and children) that may involve excluded relevant material:

Table Four – Novel Transplants (Adults)	
Case	Meaning of express consent
1. The adult is alive.	The adult’s consent.
2. The adult has died and a decision of the adult to consent, or not to consent, to the activity was in force immediately before death.	The adult’s consent.
3. The adult has died, case 2 does not apply, the adult had appointed a person or persons to deal with the issue of consent in relation to the activity and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.
4. The adult has died, case 2 does not apply and the adult had appointed a person or persons to deal with the issue of consent in relation to the activity, but no one is able to give consent under the appointment.	Consent of a person who stood in a qualifying relationship to the adult immediately before death.

5. The adult has died and none of cases 2, 3 or 4 applies in relation to the adult.	Consent of a person who stood in a qualifying relationship to the adult immediately before death.
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Table Five – Novel Transplants (Children)	
Case	Meaning of express consent
1. The child is alive and case 2 does not apply.	The child's consent.
2. The child is alive, no decision of the child to consent, or not to consent, to the activity is in force, and either the child is not competent to deal with the issue of consent or is competent to deal with the issue but fails to do so.	Consent of a person who has parental responsibility for the child.
3. The child has died and a decision of the child to consent, or not to consent, to the activity was in force immediately before death.	The child's consent.
4. The child has died, case 3 does not apply, the child had appointed a person or persons to deal with the issue of consent in relation to the activity and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.
5. The child has died, case 3 does not apply and the child had appointed a person or persons to deal with the issue of consent in relation to the activity, but no one is able to give consent under the appointment.	Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person in a qualifying relationship to the child at that time.

<p>6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.</p>	<p>Consent of a person who had parental responsibility for the child immediately before the child died, or where no such person exists, the consent of a person in a qualifying relationship to the child at that time.</p>
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Further information

This section provides information which will primarily be relevant to SNODs and practitioners.

Information on the terminology used in this Code of Practice

138. Where the words “organ” or “organs” are used in this Code of Practice, they mean organs, part organs and tissue.
139. Where the phrase “organ donation” is used, this means organ and/or tissue donation after death, unless stated otherwise.
140. Throughout this Code of Practice the actions carried out by the Specialist Nurse for Organ Donation (SNOD) are sometimes described as taking place before the withdrawal of life sustaining treatment. In some cases these actions will be undertaken by the SNOD after the decision has been made by the team treating the person that further treatment is futile, but before the person dies. In some cases they will be undertaken after the person has died. The same steps should be taken in both instances, unless stated otherwise.
141. Express consent means:
- a) the decision of a person when alive to either consent or not to consent to certain transplantation activities; or
 - b) the decision of appointed representative/s on behalf of that person; or
 - c) the decision of someone with parental responsibility (when the person is a child); or
 - d) the decision of someone in a qualifying relationship with that person.
142. When the phrase “fact and degree” is used, it means that the information presented and the information gained through questioning will need to be weighed up based on the quality of the facts and the quantity of information.
143. An appointed representative means a person appointed under section 8 of the Human Transplantation (Wales) Act.
144. Relevant material for the purpose of the Human Transplantation (Wales) Act is defined as material, other than gametes, which consists of or includes human cells.
145. In this Code of Practice, the word ‘must’ refers to an overriding statutory duty or principle, including all specific legal requirements derived from primary and

secondary legislation.

146. The word 'should' is used to explain how to meet the specific legal requirements. Establishments and practitioners are expected to follow the statutory guidance in the Code of Practice.

Other documents which provide advice and guidance in this area

147. The HTA, as the statutory regulator, is required to provide advice and guidance on the Human Transplantation (Wales) Act.
148. There is a range of guidance and documentation on organ donation, transplantation and related matters which may be helpful to those using this Code of Practice.
149. These include (at the time of publication):
- a) [HTA Codes of Practice](#)
 - b) [HTA framework document on the quality and safety of organs intended for transplantation](#)
 - c) [HTA guidance on living organ donation](#)
 - d) [HTA guidance on tissue and cells for patient treatment](#)
 - e) [Organ Donation \(CG135\) – NICE Guidelines](#)
 - f) [UK Donation Ethics Committee on Donation after Brainstem Death](#)
 - g) [UK Donation Ethics Committee on Donation after Circulatory Death](#)
 - h) [Department of Health guidance on legal issues relevant to Donation after Circulatory Death](#)
 - i) [Academy of Medical Royal Colleges Code of Practice on the diagnosis of death](#)
 - j) [Mental Capacity Act 2005 Code of Practice](#)
 - k) [Coroners and organ donation guidance](#)

Who can confirm or seek consent

150. Throughout this Code of Practice when reference is made to a person confirming or seeking consent for organ donation, they are referred to as a SNOD. This reflects the [National Institute for Health and Care Excellence \(NICE\) guidelines](#) on consent for organ donation and NHS Blood and Transplant's (NHSBT) policies and processes.
151. This does not mean that only a SNOD can confirm or seek consent. However, if the person seeking consent is not a SNOD, it is recommended that they meet the criteria in recommendations 1.1.30 and 1.1.31 of the NICE guidelines on consent and be competent in understanding the legislation and this code of practice.
152. SNODs operate as part of a multi-disciplinary team at the hospitals in which they work, and decisions on organ donation are taken in consultation with relevant colleagues.
153. SNODs are employees of NHSBT and when they are required to make a difficult decision, or encounter a novel situation, there are NHSBT decision-making processes in place to support them. This means that SNODs are always able to discuss the situation with colleagues and if necessary contact a member of the senior management team to make the final decision. This is aimed at ensuring consistency of approach and high-quality decision making.
154. Consideration should be given to the needs of family/friends who are providing information and/or giving consent whose first language is not English or Welsh. Any difficulties in communicating with the person interviewed (e.g. because of language, literacy or hearing difficulties), and an explanation of how these difficulties were overcome (e.g. through an independent translator), should be recorded.

Legislative frameworks

Deceased organ donation

155. The Human Transplantation (Wales) Act makes provision for the consent (whether deemed or otherwise) that is required for all aspects of deceased organ donation carried out for the purpose of transplantation, for people who both live (are ordinarily resident) and die in Wales.
156. There are circumstances when consent to organ donation in Wales cannot be deemed, for example when the donor is under the age of 18 or when the person had made a decision in life in regard to organ donation, and in such cases express consent is required before organ donation can proceed.
157. The meaning of express consent will depend on the circumstances of the donation. For example, if a person had made a decision about consent before their death then this will be express consent. Alternatively, if the person had not made such a decision then express consent means the consent of any appointed representative/s or the consent of a person or people in a qualifying relationship, or the consent of a person with parental responsibility in the case of children.

Living organ donation

158. The current UK law on living organ donation is set out in the Human Tissue Act and the Human Tissue (Scotland) Act and regulations made under them. The Human Transplantation (Wales) Act does not operationally change this. More information on consent to living organ donation can be found in the [HTA Code of Practice](#).
159. However, the Human Transplantation (Wales) Act does cover other aspects of the living donation process, in particular the storage and use of organs for the purpose of transplantation. For these activities, the living donor's express consent will be needed.

Research

160. Deemed consent does not apply to the donation of organs for research purposes.
161. It is common practice for a discussion on the removal and use of organs for research to take place between a SNOD and the family/friends of the deceased when information is being gathered to facilitate organ donation. As

consent/authorisation to research continues to be governed by the Human Tissue Act in England, Wales and Northern Ireland, and the Human Tissue (Scotland) Act in Scotland, express consent from the highest ranking person on the qualifying list (found in section 27(4) of the Human Tissue Act) will be required for the removal of material for the purpose of research (or any other scheduled purpose) to be lawful (unless the person made a decision in life in regard to research, or nominated a representative to do so on their behalf).

Licensing arrangements

162. Since August 2012 establishments which carry out organ donation and/or transplantation activities must be licensed under the Quality and Safety of Organs Intended for Transplantation Regulations (the Regulations).
163. The HTA is the Competent Authority for the whole of the UK, and carries out audits to ensure establishments are compliant with the requirements of the Regulations. One of the HTA's audit assessment criteria relates to verifying consent is in place prior to the organ being retrieved.
164. In order to meet the HTA's standards on consent, an establishment located in any part of the UK must be able to demonstrate that it has in place policies and practices which ensure that legal requirements relating to consent/authorisation are met, whether this is under the Human Transplantation (Wales) Act, the Human Tissue Act, or the Human Tissue (Scotland) Act.

Use of organs and tissue across borders

165. Prior to 1 December 2015, legislative provision will be made to allow the use of organs and tissue removed in Wales under the Human Transplantation (Wales) Act in England and Northern Ireland. No such provision is required for Scotland.
166. This will mean that organs and tissue removed under deemed consent can be lawfully transplanted into patients in England, Northern Ireland and Scotland (providing all other statutory and regulatory requirements have been met).
167. This also means the organs and tissue removed in Wales for the purpose of transplantation under deemed consent can be stored, used, processed and distributed lawfully across the whole of the UK.
168. Material removed under deemed consent for the purpose of transplantation, which cannot be used for this purpose, can be used for research if consent to this is obtained as per the requirements of the Human Tissue Act.

Types of organ donation after death

169. There are two types of organ donation after death which are undertaken in the UK. In Wales consent to either Donation after Brainstem Death (DBD) or Donation after Circulatory Death (DCD) can be deemed under the Human Transplantation (Wales) Act.

Donation after Brainstem Death

170. Donation after Brainstem Death (DBD) means donation which takes place following tests that have established that the person no longer has any brainstem function. Patients declared brainstem dead may have suffered head trauma, for example in a car accident, or a stroke. The patient's organ support, including mechanical ventilation, is maintained while consent is established or sought and (where applicable) arrangements are put in place for organ donation.

Donation after Circulatory Death

171. Donation after Circulatory Death (DCD) means donation which takes place following the diagnosis of death by cardio-respiratory criteria.

172. DCD may be either controlled or uncontrolled. Controlled DCD describes organ retrieval which follows the planned withdrawal of life-sustaining treatment at the end of a critical illness from which the person cannot recover. Uncontrolled DCD occurs following a sudden, irreversible cardiac arrest.

Transplantation activities

173. For the purposes of the Human Transplantation (Wales) Act, transplantation activities are as follows:

- a) Storing the body of a deceased person for the purpose of transplantation. For example, if the body remains in the Intensive Care Unit for a period of time before retrieval can begin.
- b) Removing from the body of a deceased person, for the purpose of transplantation, any relevant material of which the body consists or which it contains. For example, organs and blood vessels, spleen and lymph nodes.
- c) Storing for use for transplantation any relevant material which has come from a human body.
- d) Using for transplantation any relevant material (see paragraphs 178 to 180) which comes from the human body.

174. Deemed consent can apply to any of the transplantation activities at a to d above, if the conditions in the rest of this Code of Practice are met.

175. The storage and use of relevant material for the purpose of transplantation is lawful without the need for consent in Wales when the material has been lawfully imported into Wales, and lawful removal of the material from a person's body took place outside Wales.

176. This means that when an organ is imported into Wales from another country it is not necessary for consent to be sought in Wales in order for the organ to be stored or used. However, as the statutory regulator for England, Wales and Northern Ireland the HTA advises that:

- a) When the organ is imported from England or Northern Ireland consent under the Human Tissue Act must be in place.
- b) When the organ is imported from Scotland authorisation under the Human Tissue (Scotland) Act must be in place.

177. When the organ is imported from another country the HTA recommends it is best

practice to ensure that consent for donation for transplantation was in place in-line with the legal framework in operation in that country.

Relevant material

178. Relevant material for the purpose of the Human Transplantation (Wales) Act is defined as material, other than gametes, which consists of or includes human cells.

179. Relevant material from a human body, does not, for the purposes of the Human Transplantation (Wales) Act include:

- a) Embryos outside the human body, or
- b) Hair and nail from the body of a living person.

180. More information on relevant material can be found on the [HTA website](#).

Preservation for transplantation

181. The Human Transplantation (Wales) Act allows for steps to be taken to preserve the organs within the body of a deceased person when it is, or may be, suitable for transplantation, but consent or the absence of consent has not yet been established.
182. Please note that the provisions relate only to the preservation of a deceased person's body after their death. Information on interventions prior to death is provided at paragraphs [187 to 191](#).
183. In order for preservation to be lawful, the body of the deceased person must be lying in a hospital, nursing home or other institution in Wales. For the purpose of this section "in Wales" has the same meaning as in paragraph 44, and means within a Welsh local authority area.
184. The steps which can be taken to preserve the organs within the body for transplantation must be minimal and there is an obligation that the least invasive procedure is used.
185. The taking and storage of blood samples from a deceased person for the purpose of facilitating organ donation for transplantation is acceptable, as without such samples it is unlikely donation could go ahead if it is discovered that consent is in place. A licence under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 must be in place in order for such blood samples to be tested lawfully.
186. If it is established that express consent is not in place, and that consent cannot be deemed for the person, then the steps to preserve for the purpose of transplantation should cease or be withdrawn promptly, as applicable.

Interventions prior to death

187. The Human Transplantation (Wales) Act does not address the matter of steps which may be taken prior to the death of a person who may become a donor after circulatory death.
188. The steps which may be taken prior to the death of a person to facilitate DCD are detailed in the Department of Health document "[Legal issues relevant to non-heartbeating organ donation](#)" published in November 2009.
189. At the time of drafting this Code of Practice there are a number of reviews being undertaken to provide increased clarity and certainty to those working within organ donation and transplantation.
190. If the Department of Health Guidance of November 2009 is revised, an update will be provided to this Code of Practice to reflect this.
191. It is important to note that interventions before death are governed by the Mental Capacity Act 2005, rather than the Human Transplantation (Wales) Act or Human Tissue Act.

Coroners

192. Where the person's death is violent or unnatural, or is sudden and the cause is unknown, the matter of organ donation requires referral to the coroner and in such cases agreement (or a lack of objection) of the coroner should be sought before any transplantation activities can be undertaken, or steps can be taken to preserve the organs within the body of the person.

193. It is recommended that SNODs and hospital administrations seek to agree a working protocol with the coroner/s in the local area, in order that they are able to establish at an early stage whether the person's body will be under the coroner's authority, and whether the coroner will agree to steps being taken for preservation, and eventually for organ donation.

Activities involving material from living adults who lack the capacity to consent

194. Where an adult lacks the capacity to consent to the removal of an organ or part organ, the case must be referred to a court for a declaration that the removal would be lawful. Donation may then only proceed if court approval has been obtained and following court approval the case is referred to, and assessed by, an HTA panel.
195. The Human Transplantation (Wales) Act does not specify the criteria for considering whether an adult has capacity to consent to the removal of an organ or part organ. The relevant legislation is the Mental Capacity Act.
196. If the conditions of Regulations made by Welsh Ministers are satisfied, it would be possible to deem the consent of the person. The HTA will provide guidance on such Regulations once they have been made. [The guidance will be made available on the HTA's website.](#)

Offences

197. A person commits an offence under the Human Transplantation (Wales) Act if they undertake a transplantation activity without consent.
198. This means that if a body is stored, or if relevant material is removed, stored or used for the purpose of transplantation without consent, then the person who carried out that activity will have committed an offence.
199. An offence is committed by a person if they represent to someone who either will or may undertake a transplantation activity that there is consent to that activity, or that the activity is not a transplant activity, when they know the representation to be false or do not believe it to be true.
200. In order to be guilty of an offence the person who made the representation must have known it to be false. If they reasonably believed they were acting correctly and in good faith then they will not have committed an offence.
201. For the purpose of offences under the legislation, consent means either express or deemed, depending on which type of consent should have been relied upon.
202. The person who committed the offence will be subject to a fine not exceeding the statutory maximum if summarily convicted.
203. If convicted on indictment, the person who committed the offence will be subject to:
 - a) Imprisonment for a term not exceeding three years, or
 - b) A fine; or
 - c) Both.
204. If a person reasonably believed they were undertaking a transplant activity with consent, or they reasonably believed the activity they were undertaking was not a transplant activity, then no offence has been committed.
205. The test associated to reasonably believing is a subjective one. In order to prove that a person reasonably believed that consent was in place or the activity they had undertaken was not a transplantation activity, they would need to produce evidence which would satisfy a court.
206. As the Human Transplantation (Wales) Act was not in force at the time of drafting this Code of Practice, there is as yet no case law which provides

information on the types of evidence which would satisfy a court that the person had a reasonable belief in regard to consent for organ donation.

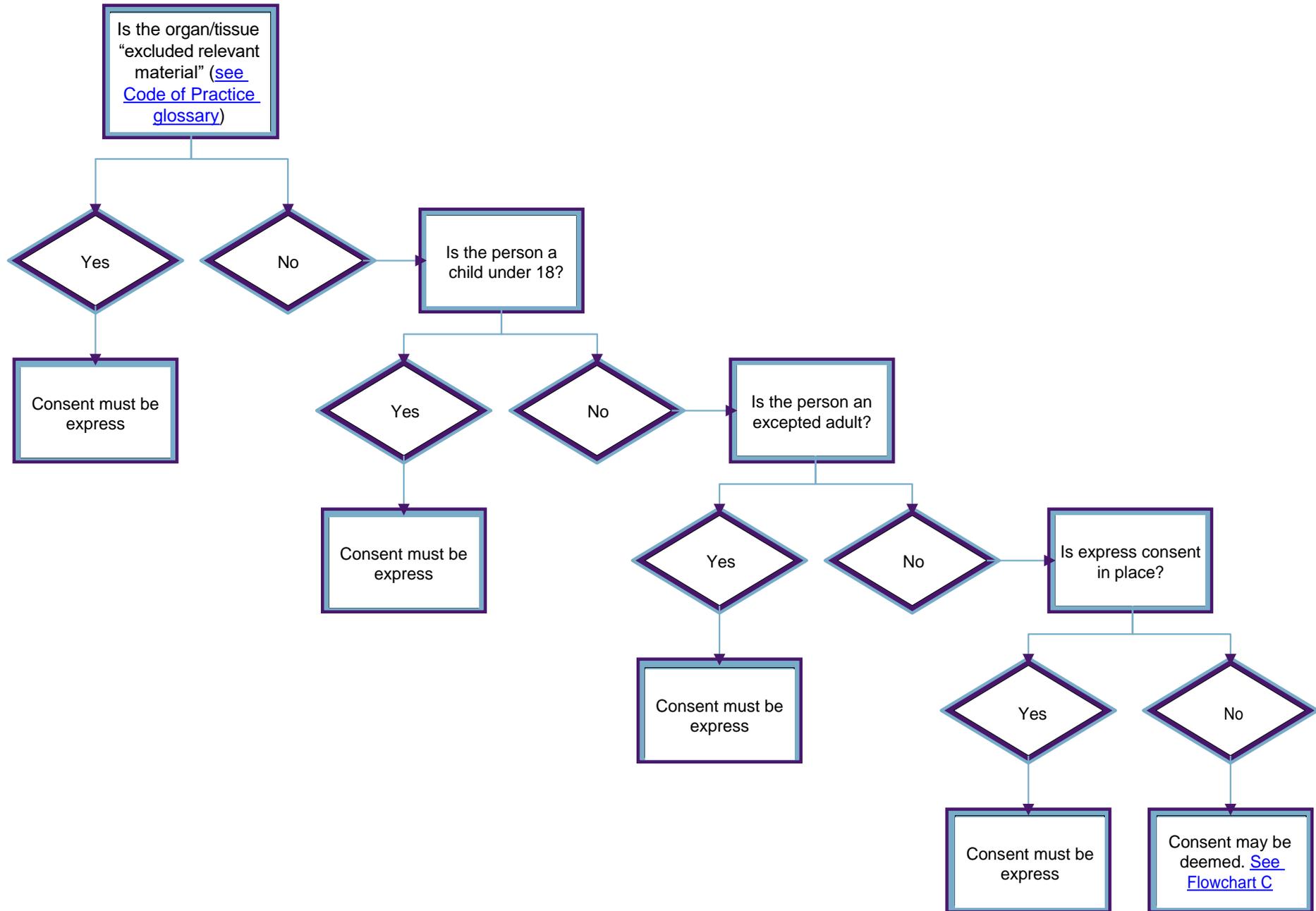
Glossary

Term	HTA definition
Authorisation	In respect of a donor in Scotland , where the donor is an adult with capacity to give authorisation, Part 1 of the Human Tissue (Scotland) Act 2006; or the authorisation or lack of unwillingness of the donor referred to in, the Human Organ and Tissue Live Transplants Scotland Regulations 2006 (SI 2006 no. 390).
Child	A person who has not attained the age of 18 years.
Deemed consent	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.
Donor	A person who donates one or several organs and/or tissue, whether donation occurs during lifetime or after death.
Donation	Donating organs or tissue for the purposes of transplantation.
Express consent	<ul style="list-style-type: none"> • the decision of a person when alive to either consent or not to consent to certain transplantation activities; or • the decision of 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

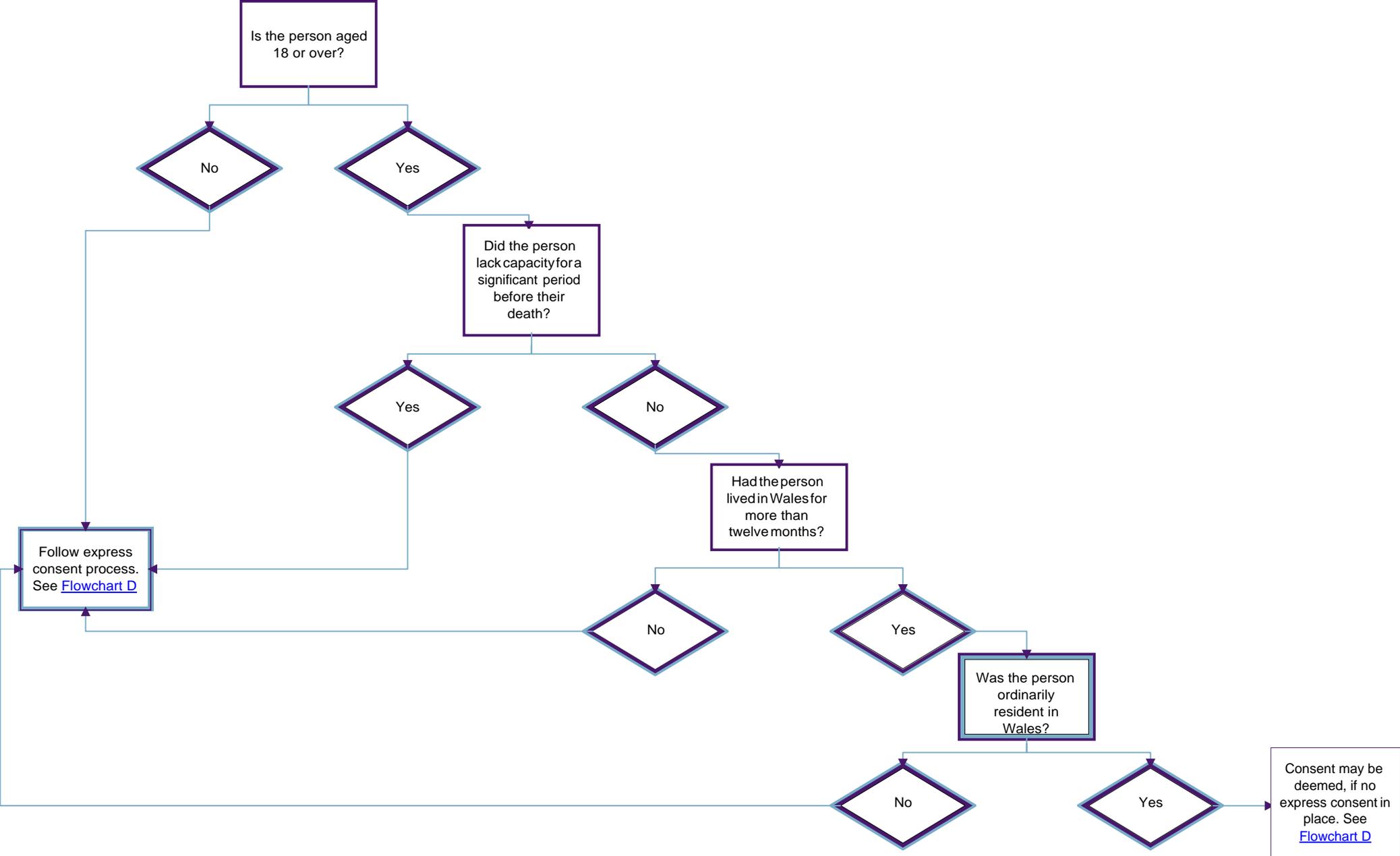
	person.
Excluded relevant material	Organs and tissues which are listed in the Regulations made by Welsh Ministers and for which consent to donation for transplantation cannot be deemed.
Human Tissue Authority	The statutory regulator that licenses organisations that store, use and remove human tissue for purposes including research, patient treatment, post- mortem examination, teaching and public exhibitions. It also assesses and makes decisions on organ and bone marrow donations from living people.
Novel transplant	The transplantation of an organ or tissue which is on the list contained in the Regulations on novel transplants drafted for the purpose of section 7 of the Human Transplantation (Wales) Act.
ODR	The organ donor register.
Organ	A differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation. (Please note, where the words “organ” or “organs” are used in this Code of Practice, they mean organs, part organs and tissue.)
Parental responsibility	All the rights, duties, powers and responsibility which a parent of a child has in relation to the child and their property. The categories of persons with parental responsibility are as set out in the Children Act 1989.

Reasonable person test	An objective test, and involves weighing up the information available on the given matter.
Research	A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body.
A Specialist Nurse for Organ Donation (SNOD)	A nurse responsible for promoting and facilitating the organ donation process and providing support and appropriate information to families.
Tissue	Any and all constituent part/s of the human body formed by cells.
Transplantation	A process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient.

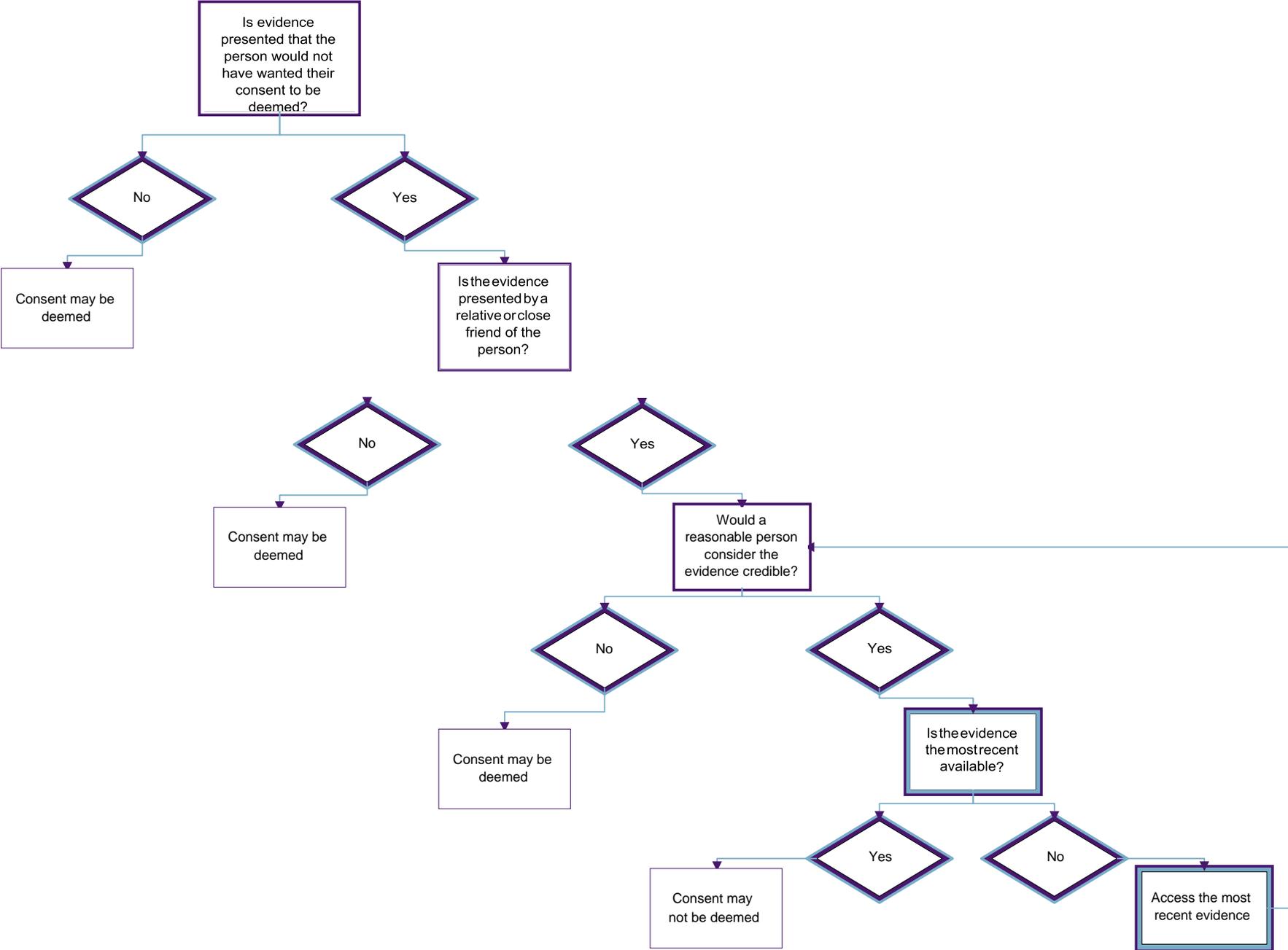
Flowchart A - Overview of deemed and express consent



Flowchart B - Can deemed consent apply to the person?



Flowchart C - is there evidence to overturn deemed consent?



Flowchart D - Express consent process

