

# **HUMAN TRANSPLANTATION (WALES) ACT 2013**

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## **EXPLANATORY NOTES**

### **INTRODUCTION**

1. These Explanatory Notes are for the Human Transplantation (Wales) Act 2013, which was passed by the National Assembly for Wales on 2 July 2013 and received Royal Assent on 10 September 2013. They have been prepared by the Department for Health and Social Services of the Welsh Government to assist the reader of the Act. The Explanatory Notes should be read in conjunction with the Act but are not part of it.

### **BACKGROUND AND SUMMARY**

2. Prior to the coming into force of the Human Transplantation (Wales) Act 2013 all statutory provisions on consent for the use of bodies and relevant materials were set out in the Human Tissue Act 2004 (the 2004 Act), which applies to Wales, England and Northern Ireland. The 2004 Act authorises certain activities, including the removal and use of organs and tissues, for a number of purposes that are set out in Schedule 1 to that Act. One of these is use for the purpose of transplantation. Under the 2004 Act “appropriate consent” is required for the use of organs and tissues for the purposes listed in the Schedule. The meaning of appropriate consent differs depending on whether the relevant material is obtained from an adult or child, but the overarching principle is that the consent must be given expressly.
3. The purpose of the Human Transplantation (Wales) Act 2013 is to change the way in which consent is to be given to organ and tissue donation in Wales, for the purposes of transplantation. The Act provides that, in the absence of express provision in relation to consent, consent will be deemed to have been given in most cases. This means that, after death, a person’s consent will be deemed to have been given unless they had expressed a wish for or against donation. However, deemed consent does not apply to the under 18s, people who have not lived in Wales for at least 12 months before they died, and people who lack capacity to understand that consent could be deemed in the absence of express action being taken. In addition, in practice people who cannot be identified or whose next of kin cannot be found will not be subject to deemed consent, since it would not be possible to check whether the person satisfied key criteria including residency.

4. The Act therefore creates a default position where adults are considered (deemed) to have given their consent unless they object. However, consent will not be deemed where a relative or friend of long standing objects on the basis they knew that the deceased would not have consented to their organs and tissues being donated for the purpose of transplantation. This is what is often referred to as a “soft opt-out system” for organ and tissue donation. The notion of “appropriate consent” from the 2004 Act is therefore replaced by two concepts, “express consent”, (which replicates “appropriate consent”) and “deemed consent”.
5. There are several exceptions to deemed consent, including children, those who are not ordinarily resident in Wales and those who lack capacity to understand the notion of deemed consent. Where deemed consent will not apply, the Act generally restates the meaning of the concept of appropriate consent set out in the 2004 Act. This means the status quo will remain for a person who dies in Wales but who is not subject to deemed consent. In summary, therefore, with the exception of deemed consent applying in Wales, the system of express consent in England, Northern Ireland (and in certain cases in Wales) remains the same.

#### **TERRITORIAL APPLICATION**

6. The Welsh legislation applies in relation to consent where a transplantation activity takes place in Wales. The 2004 Act applies in all cases relating to consent for the purposes of transplantation where the activity takes place in England or Northern Ireland.
7. The Act sets out in one place the main provisions relating to consent for transplantation activities in Wales. As a result, the Act restates certain sections of the 2004 Act directly related to consent for the purposes of transplantation. However, in order to maintain an effective cross-border regime in terms of the operation of the UK-wide organ transplantation programme, there is an inevitable interplay with the 2004 Act. Certain other provisions of the 2004 Act not directly related to consent but applicable to transplantation, have not been restated but continue to apply in Wales. These include provisions relating to the Human Tissue Authority and sections 8 (restriction of activities in relation to donated material), 33 (restriction on transplants involving a live donor) and 34 (information about transplant operations) of the 2004 Act.

## **COMMENTARY ON SECTIONS**

### **Section 1: Overview**

8. This section summarises the main provisions of the Act. It is intended to sign post readers to relevant sections.

### **Section 2: Duty of the Welsh Ministers to promote transplantation**

9. Although subsection (1) is partly general in its application (promoting transplantation as a means of improving health), it also contains an important specific duty on Welsh Ministers to educate those resident in Wales (and potentially those likely to become resident) about the circumstances in which consent can be deemed. This is important because inaction amounts, in effect, to consent. This provision is not expressly confined to Wales (as a geographical concept) due to there being a need for flexibility in relation to where promotional and educational activity takes place.
10. This subsection also includes a duty on the Welsh Ministers to ensure Local Health Boards in Wales have the requisite resources in place in terms of staff with the specialist skills and competencies required to facilitate transplantation. However, the duty does not require the Welsh Ministers to provide any specific level of “ring-fenced” funding to Local Health Boards.
11. Subsection (2) clarifies that the Welsh Ministers’ duty under subsection (1) includes carrying out annual communications activities to educate people in Wales about the system introduced by the legislation.
12. Subsection (3) provides that the Welsh Ministers must also report annually to the National Assembly on the tasks undertaken to fulfil the duty under subsection (1). This applies only for the first five years after the Act receives Royal Assent.

### **Section 3: Authorisation of transplantation activities**

13. This is the key provision which provides that consent is required in order to carry out a transplantation activity. It introduces the concepts of deemed and express consent. It also sets out the transplantation activities to which the consent applies. It follows a similar structure to the Human Tissue Act 2004 (the 2004 Act) in that certain activities are lawful if done with consent, with the means by which consent is given in various circumstances following in subsequent sections.
14. This section provides that certain activities undertaken for the purpose of transplantation are lawful if done with, either express consent or deemed consent. The subsequent sections (4, 5, 6 and 9) set out what is meant by express and deemed consent where the person to whom the consent relates is an adult, an excepted adult (i.e. an adult to whom deemed consent cannot apply), a child or a living adult who lacks capacity.

15. The activities themselves are again based on those contained in section 1 of the 2004 Act.
16. Subsection (3) makes the storage and use of relevant material lawful where organs and tissues have been imported into Wales from outside Wales. In such cases consent is not required, meaning that all that a person using organs need be satisfied about is that the organ has been imported. This replicates the position under the 2004 Act where an organ has come into England, Wales or Northern Ireland from elsewhere (for example from Scotland).

#### **Section 4: Consent: adults**

17. This section introduces the concept of deemed consent. Deemed consent is the default position in all cases apart from excepted adults (see section 5) and children (see section 6).
18. Where deemed consent can apply, there are three possible exceptions to its application. These are:

##### **Exception 1:**

19. Table 1 sets out the cases when consent must be provided expressly, and by whom:
  - a) where the adult is alive it is the adult who must give consent meaning that deemed consent can never apply when an adult is alive. However, section 9 applies in cases where a living person lacks capacity to give consent;
  - b) where the adult has died but a decision of his or hers whether or not to consent to transplantation was in force immediately before death – in such cases that decision prevails;
  - c) the adult has died, no decision of his or hers is in force, but the adult has appointed another person or persons to take the decision under section 8 of the Act. If someone is able to give consent under the appointment, they make the decision;
  - d) the adult has died, no decision of his or hers is in force, and they appointed another person or persons to take the decision under section 8 of the Act. If no-one is able to give consent under the appointment, the decision on consent falls to qualifying relatives in ranked order, as in the Human Tissue Act 2004 (the 2004 Act). For an explanation of “qualifying relationship”, see paragraph 32 below and section 19.
20. The factual concepts behind consent are the same in this Welsh Act as is the case in the 2004 Act and reflect an intentional interplay between the two pieces of legislation. For example, the factual question of whether there is “a decision of a person to consent, or not to consent, to a [transplantation] activity .... in force immediately before his or her death” is the same whether the legal framework is the Welsh legislation or the 2004 Act. In this way, the two pieces of legislation are intended to sit side by side each other.

21. If a person is alive and normally lives, for example, in England and takes part in a transplantation activity in Wales, as a matter of law the Welsh Act applies. However the effect is the same, i.e. that person's consent is required, as if the 2004 Act applied.
22. If a person who normally lives in Wales dies in England, his or her consent cannot be deemed to have been given to a transplantation activity that takes place in England. The 2004 Act would apply and therefore a person in a qualifying relationship would decide in the absence of express consent. This result is achieved in two ways. The first is that the 2004 Act continues to apply where the transplantation activity takes place in England or Northern Ireland. Secondly under that Act the question of fact relating to whether a decision of the deceased relating to consent (in practice being on the Organ Donor Register) was in force when he or she died is the same.
23. Appointments of representatives nominated to take the decision relating to consent after death made under either the 2004 Act or the Welsh legislation are recognised in a cross border situation. This is done by a provision in both pieces of legislation (section 8(11) of this Act and new section 4(11) of the 2004 Act, to be inserted by an order made by the Secretary of State pursuant to section 150 of the Government of Wales Act 2006) by which appointments made under one Act can be treated as having been made under the other.

**Exception 2:**

24. Subsection (4) sets out that a relative or friend can object to consent being deemed on the basis that they knew the deceased wished to object to donation. Such an objection can be made by any relative or friend of long standing of the deceased. The person making an objection does not have to be a qualifying relative as defined in section 19 of the Act. However, any objection must be based on the known views of the deceased and not on the views of the relative or friend.
25. An objection must therefore-
  - a) be provided by a relative or friend of long standing who knew the views of the deceased in relation to consent for transplantation activities, and
  - b) be based on information provided about the deceased's wishes that indicates that the deceased would not have consented to transplantation activities. It should lead a reasonable person to conclude that the person objecting did indeed know the most recent views of the deceased.

**Exception 3:**

26. Consent cannot be deemed where the transplantation activity involves "excluded relevant material". Consent in relation to such material is dealt with in section 7.

**Section 5: Consent: excepted adults**

27. This section sets out the meaning of consent in relation to a transplantation activity for excepted adults, that is
- a) A deceased adult who has not been ordinarily resident in Wales for a period of least 12 months immediately before death; or
  - b) A deceased adult who lacked capacity for a significant period before death to understand that consent is deemed in the absence of express consent.
28. In the case of an excepted adult, express consent will always be required and deemed consent does not apply. This section replicates the existing legal position under the Human Tissue Act 2004 (the 2004 Act) and requires either the express consent of the individual, the express consent of a qualifying relative or the express consent of an appointed representative. It applies to deceased donation only, and not living donation.
29. A qualifying relationship is defined in the interpretation section (see section 19). The ranking of the list of qualifying relations is as set out in section 27(4) of the 2004 Act.
30. The term “ordinarily resident” is not defined, but it has been the subject of extensive case law. Ordinarily resident is primarily a question of degree and fact and suggests some habit of life. It is to be contrasted with extraordinary, occasional or temporary residence. The concept means a person’s abode in a particular place or country which has been adopted voluntarily and for settled purpose and part of the regular order of life for the time being, whether or short or long duration. A settled purpose could include education, business, employment, health or family. All that is necessary is that the purpose of living in a place has a sufficient degree of continuity to be properly described as settled, and apart from accidental or temporary absences.
31. In terms of a person who lacked capacity to understand that consent could be deemed, the exact duration that a person must have lacked capacity has not been specified. The period must, however, be significant. If a person had capacity for a prolonged period not long before they died then consent should be deemed. It is important to note that the capacity issue here (lacking capacity to understand that consent can be deemed) is slightly different to the capacity issue in section 9 (and in section 6 of the 2004 Act).

32. Under this section if no express provision (the cases in Table 2, including appointed representatives able to act) is made, then the decision regarding consent is taken by a qualifying relative. This is the same as the position under the 2004 Act. Qualifying relatives are defined in this Act (see section 19) but the ranking given to them (i.e. which relative takes the decision) is (still) done under the 2004 Act. Under section 26 of the 2004 Act the Human Tissue Authority must issue a code of practice for the purpose of “giving practical guidance” and “laying down the standards expected” in carrying on activities with bodies and organs (including transplantation). Section 26(3) of the 2004 Act includes a specific provision to say that the Code must deal with the issue of consent. Section 27 goes on to provide that the Code must “include provision to the effect” set out in subsections (4) to (8), which includes ranking and other related practical matters, though the Authority may by virtue of subsection (3) include provision of different effect in “exceptional cases”. These 2004 Act provisions will continue to apply in Wales in respect of express consent given by qualifying relatives, but the Code of Practice will make clear that relatives and friends of long standing will not be ranked for the purposes of information provided under section 4(4)(b) of this Act. See section 15 for more detail on the Code of Practice.
33. As to the cross border effect, this section is intended to work such that if somebody who ordinarily lives in England or elsewhere dies in Wales, and therefore the transplantation activity is done in Wales, the legal position is the same as if they had died in England. This position is achieved as the question of fact relating to whether a decision of the deceased relating to consent (in practice being on the Organ Donor Register) was in force when he or she died is the same.
34. As in section 4, this section does not cover consent for transplantation activities involving excluded material which is dealt with in section 7.

### **Section 6: Consent: children**

35. Section 6 sets out the arrangements that apply to children and young people aged under 18 who die in Wales. These restate the provisions in section 2 of the Human Tissue Act 2004 (the 2004 Act), except that under this Act children and young people are able to appoint one or more representatives to take a decision on consent, in the same way as adults. For children and young people, either their own express consent will apply, or if that has not been given (and they have not appointed a representative able to act), the consent of a person with parental responsibility will apply. Where no such person exists then the consent of a person standing in a ranked qualifying relationship to them, as provided for in section 27(4) of the 2004 Act, must be given.

36. Where children make any decision on consent, the decision is effective only if they are competent to take such a decision. In the interpretation section (section 19(2)) competence is defined in this context as meaning where it would appear to a reasonable person that the child has sufficient understanding to make an informed decision. This test of competence also applies to consent to transplantation activities involving excluded materials (see section 7) and to a child appointing representatives to take the decision on consent after the child's death (see section 8).

### **Section 7: Consent: transplantation activities involving excluded material**

37. This section provides that Welsh Ministers may make regulations specifying "excluded relevant material" and sets out that express consent is required in relation to transplantation involving any such specified material. It gives as possible examples of such material the transplantation of composite tissues or other forms of transplantation that would be considered novel at the time the regulations are made. Faces and limbs are examples of "composite tissues". However, since these are examples, regulations need not include them or may specify that other forms of material are to be excluded.
38. Consent for transplantation activities involving excluded material cannot be deemed. Where consent is required under this section, in the case of adults, consent may be given by the person themselves or an appointed representative able to act, or otherwise consent may be given by a qualifying relative. In the case of children, consent may be given by the child themselves if competent to do so, or an appointed representative able to act, or otherwise consent may be given by a person with parental responsibility. If there is no person with parental responsibility, the decision on consent in these cases would be taken by a qualifying relative.

### **Section 8: Appointed representatives**

39. This section provides that a person may appoint a representative or representatives to give consent to any of the activities set out in section 3. This section replicates section 4 of the Human Tissue Act 2004 (the 2004 Act) but with three differences. Firstly the Welsh legislation recognises an appointment made under the 2004 Act. The second is that it is Welsh Ministers who will hold the power to prescribe in regulations that persons of a particular description cannot act under an appointment in relation to somebody who dies in Wales (the equivalent power in the 2004 Act is held by the Secretary of State). Finally, by use of the word "person", this section recognises that in Wales a child may also appoint a representative.
40. An appointment made under this Act will be recognised by the 2004 Act (once relevant amendments have been made to that Act by the Secretary of State pursuant to section 150 of the Government of Wales Act 2006) and similarly an appointment made under the 2004 Act is recognised by this Act. It does not therefore matter whether the activity would take place in England, Wales or Northern Ireland.

41. Section 8(12) specifies that if it is not reasonably practicable to communicate with an appointed representative, in time for consent to be acted on, then the appointed representative is treated as not able to give consent. In these circumstances the decision on consent would pass to qualifying relatives.

### **Section 9: Activities involving material from (living) adults who lack capacity to consent**

42. This section applies where a living adult lacks capacity to consent to donation and no decision is in force. This section has the same effect as section 6 of the Human Tissue Act 2004, except that the power to prescribe in regulations when deemed consent can apply is held by the Welsh Ministers as regards a transplantation activity in Wales. This power could be used to prescribe that consent could only be deemed if it is in the best interests of the living adult. For example, it could be in the best interests of the person who lacks capacity to donate relevant material to a close relative. Deemed consent in this context is different from the deemed consent provisions set out in section 4, which relate to deceased donors. However, the basic premise of taking action without the express consent of the individual is the same.

### **Section 10: Prohibition of activities without consent**

43. This section makes it a criminal offence in Wales to undertake the transplantation activities set out in section 3 without consent. A person has a valid excuse, however, if the person concerned reasonably believed that consent was in place. This is the main enforcement provision of the Act and is based on section 5 of the Human Tissue Act 2004 (the 2004 Act). As the provision is built on a slightly different foundation than the 2004 Act (there being no exact equivalent of “appropriate consent” in the Act) there is a need to expressly exclude other provisions in the Act which make transplantation activities lawful without consent. This explains the reference to section 3(3) and section 13(1).
44. Subsection (5) specifies the meaning of the consent that is required. This is a question of fact and includes consent given or obtained before the coming into force of this Act.

### **Section 11: Offences by bodies corporate**

45. This section is based on a similar provision in section 49 of the Human Tissue Act 2004.

### **Section 12: Prosecutions**

46. This relates to the criminal offences that can be committed under this Act and replicates the effect of section 50 of the Human Tissue Act 2004.

### **Section 13: Preservation for transplantation**

47. This section replicates the effect of section 43 of the Human Tissue Act 2004 (the 2004 Act). This section makes it lawful to retain the body of a deceased person and preserve organs in the body which may be suitable for transplantation, while the issue of consent (whether express or deemed) to the use of organs is resolved. The actions taken for preservation must involve the minimum steps necessary and the least invasive procedures. Whilst this is not directly related to consent it is inherent to how the system works before it is established whether consent exists and has therefore been restated in this Act. An amendment has been made to the corresponding section 43 of the 2004 Act to make clear which provision applies (i.e. the one in this Act).

### **Section 14: Coroners**

48. In order to maintain the current legal position regarding coroners, this section exempts from the requirements of the Act anything done for the purposes of the functions of a coroner, or under his authority. This section provides that before acting on authority under section 3 or section 13, if a body or relevant material is or may be required for the purposes of the functions of the coroner, the coroner's consent is required. This section replicates the effect of section 11 of the Human Tissue Act 2004.

### **Section 15: - Codes of practice**

49. The Human Tissue Authority (the Authority) is required to issue a code of practice which includes practical guidance and standards. The provisions relating to the Code of Practice set out in the Human Tissue Act 2004 (the 2004 Act) have not been replicated or restated in the Act as there is only one Authority and one Code. This section therefore amends the 2004 Act to reflect the Welsh legislation. This includes a power for Welsh Ministers to amend by statutory instrument the ranking of those in a qualifying relationship to the deceased and a requirement for the Code to give guidance on how a relative or friend of the deceased can object to deemed consent on the basis of the deceased's wishes (see section 4).
50. The amendments to the 2004 Act also mean that the Authority may not issue a code which relates to activities caught by the Welsh legislation unless a draft has been approved by both Welsh Ministers and the National Assembly for Wales (the latter subject to affirmative resolution).

### **Section 16: Consequential and incidental amendments to the Human Tissue Act 2004**

51. This section makes a number of amendments to the Human Tissue Act 2004 (the 2004 Act) which are consequential or incidental to this Act. As a consequence section 1(1) of the 2004 Act will no longer apply to consent for transplantation activities carried out in Wales.

52. Other amendments disapply sections of the 2004 Act which have been restated for Wales in this Act, for example, sections 6 (adults who lack capacity), and section 43 (preservation for transplantation).
53. Amendments are also made so that the general functions of the Human Tissue Authority (the Authority) and its annual report take account of this Act. The Authority's powers of inspection, entry, search and seizure are also amended so as to incorporate situations covered by the Act.
54. The effect of Schedule 11 to the Government of Wales Act 2006 was to change references to the "National Assembly for Wales" to "'Welsh Ministers". This section actually amends the text of 2004 Act to make this change, so as to assist the reader. New requirements for Welsh Ministers to lay documents before the National Assembly for Wales have also been added to reflect the new constitutional arrangement post the Government of Wales Act 2006 (so that they replicate the provisions for the Northern Ireland Assembly and the UK Parliament).

### **Section 17: Consequential amendment to the Wills Act 1837**

55. This section amends the Wills Act 1837 to reflect this Act (in the same way as the Human Tissue Act 2004 is reflected) in cases where someone makes provision for an appointed representative in a will.

### **Section 18: Relevant material**

56. This section defines what is meant by the material removed from the body for the purpose of transplantation. The definition is the same as that in section 53 of the Human Tissue Act 2004.

### **Section 19: Interpretation**

57. A definition of qualifying relationship is included in addition to the reference to the ranking of those relationships in section 27(4) of the Human Tissue Act 2004. The 2004 Act defines the term (at section 54(9)) as well as giving the different relationships that form the definition a ranking through section 27(4) and the Code of Practice issued by the Human Tissue Authority. Relatives and friends of long standing will not be ranked for the purposes of section 4(4)(b) of this Act (information that can prevent deemed consent), but qualifying relations will be ranked for all other purposes. In the definition of "qualifying relationship", the reference to a "child" is a reference to the relationship of that person to the deceased and, therefore, means the son or daughter of the deceased (no matter what that person's age). Similarly, there is no age restriction in relation to a "grandchild".

### **Section 20: Orders and regulations**

58. This section provides for the procedure that will be used for making subordinate legislation under this Act (except for commencement orders). This means that subordinate legislation may not be made unless Welsh Ministers have carried out a public consultation, and a draft has been laid before and approved by the National Assembly for Wales.

**Section 21: Commencement**

59. This section deals with the commencement of this Act once it has received Royal Assent. Section 2, which places a duty on Welsh Ministers to promote and provide information about transplantation, will be commenced on Royal Assent, as will Sections 1 (Overview); 21 (Commencement) and 22 (Short Title). The remaining provisions will be commenced no sooner than two years following Royal Assent.

**Section 22: Short title**

60. The short title of the Act is the Human Transplantation (Wales) Act 2013.

**RECORD OF PROCEEDINGS IN NATIONAL ASSEMBLY FOR WALES**

The following table sets out the dates for each stage of the Act's passage through the National Assembly for Wales. The Record of Proceedings and further information on the passage of this Act can be found on the National Assembly for Wales' website at:

<http://www.senedd.assemblywales.org/mgIssueHistoryHome.aspx?IId=5178>

<b>Stage</b>	<b>Date</b>
Introduced	3 December 2012
Stage 1 - Debate	16 April 2013
Stage 2 Scrutiny Committee - consideration of amendments	22 May 2013
Stage 3 Plenary - consideration of amendments	2 July 2013
Stage 4 Approved by the Assembly	2 July 2013
Royal Assent	10 September 2013

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