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Human Transplantation (Wales) Bill
[AS INTRODUCED]

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Human Transplantation (Wales) Bill

[AS INTRODUCED]

An Act of the National Assembly for Wales to make provision concerning the consent required for the removal, storage and use of human organs and tissue for the purpose of transplantation; and for connected purposes.

5 **Having been passed by the National Assembly for Wales and having received the assent of Her Majesty, it is enacted as follows:**

Introduction

1 Overview

The main provisions of this Act—

- (a) impose a duty on the Welsh Ministers to promote transplantation (section 2);
- 10 (b) provide that certain activities done in Wales for the purpose of transplantation are lawful if done with consent (section 3);
- (c) set out how consent is given to transplantation activities, including the circumstances in which consent is deemed to be given in the absence of express consent (sections 4 to 8);
- 15 (d) make it an offence for transplantation activities to be done in Wales without consent (section 9);
- (e) make amendments (sections 14 and 15) to the Human Tissue Act 2004, including in relation to a code of practice issued under that Act which—
 - (i) gives practical guidance to persons that do transplantation activities, and
 - 20 (ii) lays down the standards expected in relation to the doing of such activities, including how consent is to be obtained.

Promotion of transplantation

2 Duty of the Welsh Ministers to promote transplantation

The Welsh Ministers must—

- 25 (a) promote transplantation as a means of improving the health of the people of Wales,
- (b) provide information and increase awareness about transplantation, and
- (c) inform the public of the circumstances in which consent to transplantation activities is deemed to be given in the absence of express consent.

*Lawful transplantation activities***3 Authorisation of transplantation activities**

- (1) Transplantation activities are lawful if done in Wales –
- (a) with express consent where that is required (see sections 4 to 6), or
 - (b) otherwise with deemed consent (see sections 4 and 8).
- (2) The following are transplantation activities for the purpose of this Act –
- (a) storing the body of a deceased person for use for the purpose of transplantation;
 - (b) removing from the body of a deceased person, for use for that purpose, any relevant material of which the body consists or which it contains;
 - (c) storing for use for that purpose any relevant material which has come from a human body;
 - (d) using for that purpose any relevant material which has come from a human body.
- (3) A transplantation activity of the kind mentioned in subsection (2)(c) or (d) is lawful (without the need for consent) where done in Wales if –
- (a) the relevant material has been imported into Wales from outside Wales, and
 - (b) its removal from a person's body took place outside Wales.

*Consent***4 Consent: adults**

- (1) This section makes provision about consent for the purposes of section 3 in relation to a transplantation activity involving the body, or relevant material from the body, of a person who is not –
- (a) an excepted adult (see section 5), or
 - (b) a child (see section 6).
- (2) Consent is deemed to be given to the activity unless –
- (a) the case is one mentioned in the first column of Table 1 in subsection (3); in which case express consent is required, or
 - (b) subsection (4) applies.
- (3) For each case mentioned in the first column of Table 1 the meaning of express consent in relation to an activity is as provided in the second column of the table –

TABLE 1

Case	Meaning of express consent
1. The person is alive.	The person's consent.
5 2. The person has died and a decision of the person to consent, or not to consent, to the activity was in force immediately before his or her death.	The person's consent.
10 3. The person has died, case 2 does not apply and the person had appointed a person or persons to deal with the issue of consent in relation to the activity.	Consent given by the person or persons appointed.

(4) This subsection applies if—

(a) the case is not one mentioned in the first column of Table 1, and

(b) a person who stood in a qualifying relationship to the deceased immediately before death provides information that would lead a reasonable person to conclude that the deceased would not have consented.

(5) In this section a reference to the appointment of a person or persons to deal with the issue of consent is a reference to an appointment under section 7.

5 Consent: excepted adults

(1) This section makes provision about consent for the purposes of section 3 in relation to a transplantation activity involving the body, or relevant material from the body, of an excepted adult.

(2) In the case of an excepted adult express consent is required.

(3) An “excepted adult” means—

(a) an adult who has died and who had not been ordinarily resident in Wales for a period of at least 6 months immediately before dying, or

(b) an adult who has died and who for a significant period before dying lacked capacity to understand the notion that consent to transplantation activities can be deemed to be given;

and for this purpose a significant period 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.

(4) For each case mentioned in the first column of Table 2 the meaning of express consent in relation to an activity is as provided in the second column of the table—

TABLE 2

Case	Meaning of express consent
5 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 and the excepted adult had appointed a person or persons to deal with the issue of consent in relation to the activity	Consent given by the person or persons appointed
10 3. Neither case 1 nor case 2 applies in relation to the excepted adult.	Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.

(5) In this section a reference to the appointment of a person or persons to deal with the issue of consent is a reference to an appointment under section 7.

6 Consent: children

- 15 (1) This section makes provision about consent for the purposes of section 3 in relation to a transplantation activity involving the body, or relevant material from the body, of a person who is a child or has died a child.
- (2) In the case of a person who is a child or has died a child express consent is required.
- 20 (3) For each case mentioned in the first column of Table 3 the meaning of express consent in relation to an activity is as provided in the second column of the table –

TABLE 3

Case	Meaning of express consent
1. The child is alive and case 2 does not apply.	The child's consent.
5 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.
10 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.
15 4. The child has died and no decision of the child to consent, or not to consent, to the activity was in force immediately before death.	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.

7 Appointed representatives

- (1) An adult may appoint one or more persons to represent the adult after death in relation to express consent for the purposes of section 3.
- (2) An appointment may be general or limited to consent in relation to such one or more transplantation activities as may be specified in the appointment.
- (3) An appointment may be made orally or in writing.
- (4) An oral appointment is only valid if made in the presence of at least two witnesses present at the same time.
- (5) A written appointment is only valid if –
 - (a) it is signed by the person making it in the presence of at least one witness who attests the signature,
 - (b) it is signed at the direction of the person making it, in his or her presence and in the presence of at least one witness who attests the signature, or
 - (c) it is contained in a will of the person making it, being a will which is made in accordance with the requirements of section 9 of the Wills Act 1837.
- (6) Where a person appoints two or more persons in relation to the same transplantation activity, they are to be regarded as appointed to act jointly and severally unless the appointment provides that they are appointed to act jointly.

- (7) An appointment may be revoked at any time.
- (8) Subsections (3) to (5) apply to the revocation of an appointment as they apply to the making of such an appointment.
- (9) A person appointed may at any time renounce the appointment.
- 5 (10) A person may not act under an appointment if the person –
- (a) is not an adult, or
 - (b) is of a description prescribed by regulations made by the Welsh Ministers.
- 10 (11) Where a person has appointed a person or persons under section 4 of the Human Tissue Act 2004 to deal after death with the issue of consent in relation to an activity done for the purpose of transplantation, the person is also to be treated as having made an appointment under this section in relation to the activity.

8 Activities involving material from (living) adults who lack capacity to consent

- (1) This section applies where –
- 15 (a) a transplantation activity within section 3(2)(c) or (d) (storage or use of relevant material which has come from a human body) done in Wales involves relevant material from the body of a person (“P”) who –
 - (i) is an adult, and
 - (ii) lacks capacity to consent to the activity, and
 - (b) no decision of P’s to consent, or not to consent, to the activity is in force.
- 20 (2) P’s consent to the activity is to be deemed if the activity –
- (a) is done by a person who is acting in what the person reasonably believes to be P’s best interests, or
 - (b) is done in circumstances of a kind specified by regulations made by the Welsh Ministers.

Offences

9 Prohibition of activities without consent

- (1) A person commits an offence if the person does, without consent, a transplantation activity in Wales.
- (2) But a person does not commit an offence under subsection (1) if –
- 30 (a) the person reasonably believes –
 - (i) that he or she does the activity with consent, or
 - (ii) that what he or she does is not a transplantation activity;
 - (b) section 3(3) (imported material) applies;
 - (c) section 12(1) (preservation for transplantation) applies.

- (3) A person (“P”) commits an offence if, in Wales—
- (a) P falsely represents to a person whom P knows or believes is going to, or may, do a transplantation activity—
 - (i) that there is consent to the doing of the activity, or
 - (ii) that the activity is not a transplantation activity, and
 - (b) P knows that the representation is false or does not believe it to be true.
- (4) A person guilty of an offence under this section is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum;
 - (b) on conviction on indictment—
 - (i) to imprisonment for a term not exceeding 3 years, or
 - (ii) to a fine, or
 - (iii) to both.
- (5) In this section “consent” means the consent required by virtue of section 3.

10 Offences by bodies corporate

- (1) Where an offence under section 9 is committed by a body corporate and is proven to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of—
- (a) any director, manager or secretary of the body corporate, or
 - (b) any officer who was purporting to act in that capacity,
- he or she (as well as the body corporate) is guilty of the offence and liable to be proceeded against and punished accordingly.
- (2) The reference to the director, manager or secretary of the body corporate includes a reference—
- (a) to any similar officer of the body;
 - (b) where the body is a body corporate whose affairs are managed by its members, to any officer or member of the body.

11 Prosecutions

No proceedings for an offence under section 9 may be instituted except by or with the consent of the Director of Public Prosecutions.

General

12 Preservation for transplantation

- (1) Where part of a body of a deceased person lying in a hospital, nursing home or other institution in Wales is or may be suitable for use for transplantation, it is lawful for the person having the control or management of the institution—
- (a) to take steps for the purpose of preserving the part for use for transplantation, and

(b) to retain the body for that purpose.

(2) Authority under subsection (1)(a) extends only to—

(a) the taking of the minimum steps necessary for the purpose mentioned in that provision, and

(b) to the use of the least invasive procedure.

(3) Authority under subsection (1) ceases to apply once it has been established that express consent making removal of the part for transplantation lawful has not been, and will not be, given and that consent is not deemed to be given.

(4) Authority under subsection (1) extends to any person authorised to act under the authority by—

(a) the person on whom the authority is conferred by that subsection, or

(b) a person authorised under that subsection to act under that authority.

(5) An act done with authority under subsection (1) is to be treated as not being an activity to which section 3 applies.

13 Coroners

(1) Nothing in this Act applies to anything done for the purposes of functions of a coroner or under the authority of a coroner.

(2) Subsection (3) applies where a person (“P”) knows, or has reason to believe, that—

(a) the body of a deceased person, or

(b) relevant material which has come from the body of a deceased person, is, or may be, required for purposes of functions of a coroner.

(3) The consent of the coroner is required before P may act on authority under—

(a) section 3 (authorisation of transplantation activities), or

(b) section 12 (preservation for transplantation),

in relation to the body or material.

14 Codes of practice

(1) The Human Tissue Act 2004 is amended as follows.

(2) In section 26 (preparation of codes of practice)—

(a) in subsection (2)(d) after “Act” insert “and the Human Transplantation (Wales) Act 2013”;

(b) at the end of subsection (3) add “(including consent for the purposes of the Human Transplantation (Wales) Act 2013).”;

(c) in subsection (5)(b) for “National Assembly for Wales” substitute “Welsh Ministers”.

(3) In section 27 (provision with respect to consent) –

(a) in subsection (1) for “section 2(7)(b)(ii) or 3(6)(c)” substitute “a provision listed in subsection (1A)”;

(b) after subsection (1) insert –

“(1A) Those provisions are –

(a) section 2(7)(b)(ii) or 3(6)(c) of this Act;

(b) section 5(4) or 6(3) of the Human Transplantation (Wales) Act 2013.”;

(c) in subsection (4) for “section 2(7)(b)(ii) or 3(6)(c)” substitute “a provision listed in subsection (1A)”;

(d) after subsection (8) insert –

“(8A) The duty under section 26(3) shall also have effect, in particular, to require the Authority to give practical guidance on the circumstances in which consent is deemed under section 4 (consent of adults that are not excepted) of the Human Transplantation (Wales) Act 2013.”

(e) in subsection (9) after “subsection (4)” insert “, except in so far as it applies to section 5(4) or 6(3) of the Human Transplantation (Wales) Act 2013.”;

(f) after subsection (9) insert –

“(10) The Welsh Ministers may by order amend subsection (4) in so far as it applies to section 5(4) or 6(3) of the Human Transplantation (Wales) Act 2013.”.

(4) In section 29 (approval of codes) –

(a) after subsection (1) insert –

“(1A) Where a code of practice to which subsection (1) applies deals with a matter relating to the carrying on in Wales of a transplantation activity (within the meaning of the Human Transplantation (Wales) Act 2013) the Authority may not issue the code unless –

(a) a draft of it has been sent to and approved by the Welsh Ministers and laid by them before the National Assembly for Wales, and

(b) a period of 40 days has elapsed without the National Assembly resolving not to approve the draft.”

(b) in subsection (2)(a) for “National Assembly for Wales” substitute “Welsh Ministers”;

(c) in subsection (3)(a) for “National Assembly for Wales” substitute “Welsh Ministers”;

(d) after subsection (4) insert –

“(4A) If the Welsh Ministers do not approve a draft sent to them under subsection (1A), they shall give reasons to the Authority.”

(e) after subsection (6) insert –

“(7) In calculating the period mentioned in subsection (1A) no account is to be taken of any time during which the National Assembly is dissolved or in recess for more than 4 days.”

5 (5) In section 52 (orders and regulations) after subsection (4) insert –

“(4A) No order under section 27(10) may be made by the Welsh Ministers unless a draft of the instrument has been laid before, and approved by a resolution of, the National Assembly for Wales.”

15 Consequential and incidental amendments to the Human Tissue Act 2004

10 (1) The Human Tissue Act 2004 is amended as follows.

(2) In section 1 (authorisation of activities for scheduled purposes) –

(a) after subsection (1) insert –

“(1A) Subsection (1) does not apply in relation to consent for transplantation activities done in Wales.”;

15 (b) after subsection (13) insert –

“(14) In this section “transplantation activities” has the same meaning as in the Human Transplantation (Wales) Act 2013 (which makes provision in relation to consent for transplantation activities done in Wales).”.

(3) In section 6 (activities involving material from adults who lack capacity to consent) –

20 (a) the existing text becomes subsection (1), and

(b) after subsection (1) add –

“(2) This section does not apply in relation to transplantation activities done in Wales.

(For provision in these circumstances see section 8 of the Human
25 Transplantation (Wales) Act 2013).”

(4) In section 8 (restriction of activities in relation to donated material), in subsection (6) after “section 1(1) to (3)” insert “or sections 3(1) to (3) of the Human Transplantation (Wales) Act 2013”.

(5) In section 15 (general functions of the Human Tissue Authority) –

30 (a) in paragraph (c)(i) after “this Part” insert “or under the Human Transplantation (Wales) Act 2013”;

(b) in paragraph (e) for “National Assembly for Wales” substitute “Welsh Ministers”;

(c) in paragraph (f) for “National Assembly for Wales” substitute “Welsh Ministers” and for “Assembly” substitute “Ministers”.

35 (6) In section 36 (annual report) –

(a) in subsection (3)(b) for “National Assembly for Wales” substitute “Welsh Ministers”;

(b) after subsection (6) insert –

“(5A) The Welsh Ministers shall lay a copy of each report received by them under this section before the National Assembly for Wales.”.

(7) In section 43 (preservation for transplantation) after subsection (6) insert –

“(7) This section does not apply in relation to a part of a body lying in an institution in Wales.

(For provision in these circumstances see section 12 of the Human Transplantation (Wales) Act 2013).”

(8) In section 52 (orders and regulations) –

(a) in subsection (3) for “6,” substitute “6(1),”;

(b) in subsection (7)(a) for “National Assembly for Wales” substitute “Welsh Ministers”;

(c) in subsection (8) –

(i) for “National Assembly for Wales” substitute “Welsh Ministers”;

(ii) for “section 6” substitute “section 6(1)”;

(d) in subsection (10) for “section 6” substitute “section 6(1)”.

(9) In section 58 (transition), in subsection (5) for “National Assembly for Wales” substitute “Welsh Ministers”.

(10) In section 60 (commencement), in subsection (3) for “National Assembly for Wales” substitute “Welsh Ministers”.

(11) In Schedule 2 (the Human Tissue Authority) –

(a) in paragraph 1(1)(c) for “National Assembly for Wales” substitute “Welsh Ministers”;

(b) in paragraph 13(a)(ii) for “National Assembly for Wales” substitute “Welsh Ministers”;

(c) in paragraph 16(4)(b) for “National Assembly for Wales” substitute “Welsh Ministers”.

(d) after paragraph 16(5) insert –

“(5A) The Welsh Ministers shall lay before the National Assembly for Wales each statement of accounts received by them under sub-paragraph (4).”

(12) In Schedule 5 (powers of inspection, entry, search and seizure) –

(a) in paragraph 3(1)(a) after “2” insert “or under the Human Transplantation (Wales) Act 2013”;

- (b) in paragraph 5(2) after “2” insert “or under the Human Transplantation (Wales) Act 2013”.

16 Relevant material

- 5 (1) In this Act “relevant material” means material, other than gametes, which consists of or includes human cells.
- (2) In this Act references to relevant material from a human body do not include –
- (a) embryos outside the human body, or
 - (b) hair and nail from the body of a living person.
- 10 (3) In this section “embryo” and “gametes” have the same meaning as they have by virtue of section 1(1), (4) and (6) of the Human Fertilisation and Embryology Act 1990 in the other provisions of that Act (apart from section 4A).

17 Interpretation

- (1) In this Act –

15 “adult” (*“oedolyn”*) means a person who has attained the age of 18 years;

“child” (*“plentyn”*) means a person who has not attained the age of 18 years;

“parental responsibility” (*“cyfrifoldeb rhiant”*) has the same meaning as in the Children Act 1989;

20 “relevant material” (*“deunydd perthnasol”*) has the meaning given in section 16;

“transplantation activities” (*“gweithgaredd trawsblannu”*) has the meaning given in section 3.

- (2) The following are qualifying relationships for the purpose of this Act –

25 (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;

(f) stepfather or stepmother;

30 (g) half brother or half sister;

(h) friend of long standing.

- (3) For the purposes of this Act, a person is another’s partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship.

- (4) The Welsh Ministers may by order amend subsection (2).
- (5) In this Act—
- (a) references to material from the body of a living person are to material from the body of a person alive at the point of separation,
 - (b) references to material from the body of a deceased person are to material from the body of person not alive at the point of separation, and
 - (c) references to express consent include consent given before the coming into force of this Act.
- (6) In this Act, references to transplantation are to transplantation to a human body and include transfusion.
- (7) For the purposes of this Act, material is not to be regarded as from a human body if it is created outside the human body.

18 Orders and regulations

- (1) A power to make an order or regulations under this Act includes power to make such incidental, consequential, transitional or supplemental provision as the Welsh Ministers consider appropriate.
- (2) A power of the Welsh Ministers to make an order or regulations under this Act is exercisable by statutory instrument.
- (3) A statutory instrument containing an order or regulations under this Act may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, the National Assembly for Wales.
- (4) Subsection (3) does not apply to orders under section 19 (commencement).

19 Commencement

- (1) This Act comes into force in accordance with provision made by the Welsh Ministers by order.
- (2) An order made under subsection (1) may not provide for any provision of this Act to come into force before the end of the period of two years beginning with the day on which this Act receives Royal Assent.
- (3) An order made under subsection (1) may not commence the provision made in section 13(3)(b) until section 43(5A) of the Human Tissue Act 2004 has come into force.
- (4) Subsection (1) does not apply to—
- (a) section 1;
 - (b) section 2;
 - (c) this section; and
 - (d) section 20;
- which are to come into force on the day this Act receives Royal Assent.
- (5) An order made under subsection (1) may appoint different days for different purposes.

20 Short Title

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