

Human Transplantation Bill

[AS INTRODUCED]

LEGISLATIVE COMPETENCE

At Introduction the Member in charge of the Bill, Mrs Jo-Anne Dobson, had made the following statement under Standing Order 30:

“In my view the Human Transplantation Bill would be within the legislative competence of the Northern Ireland Assembly.”

Human Transplantation Bill

[AS INTRODUCED]

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Schedule Consequential amendments to the Human Tissue Act 2004

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B I L L

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.

BE IT ENACTED by being passed by the Northern Ireland Assembly and assented to by Her Majesty as follows:

Promotion of transplantation

Duty to promote transplantation

1.—(1) The Department for Health, Social Services and Public Safety (“the Department”) must—

- 5 (a) promote transplantation,
 (b) provide information and increase awareness about transplantation, and
 (c) inform the public about the circumstances where consent to transplantation is deemed to be given, and the role of relatives and friends in affirming that deemed consent.

10 (2) The duty under subsection (1)(c) includes in particular a duty to promote a campaign informing the public at least once a year.

Lawful transplantation activities

Authorisation of transplantation activities

2.—(1) Transplantation activities are lawful if done—

- 15 (a) with express consent where that is required (see sections 3, 5, 6 and 7), 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,

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- (b) removing from a human body, for use for the purpose of transplantation, any relevant material of which the body consists or which it contains,
- (c) storing for use for the purpose of transplantation any relevant material which has come from a human body,
- 5 (d) using for the purpose of transplantation 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) if—
- (a) the relevant material has been imported into Northern Ireland from outside
10 Northern Ireland, and
- (b) its removal from a person's body took place outside Northern Ireland.

Consent to transplantation activities

Express consent: adults

- 3.—(1) Where this section applies, express consent is required for a
15 transplantation activity involving the body or relevant material from the body of a person.
- (2) This section applies if—
- (a) the person is an adult, and
- (b) the case is mentioned in the first column of Table 1.
- 20 (3) The meaning of express consent for each case is set out in the second column of Table 1—

TABLE 1

	Case	Meaning of express consent
	1. The person is alive.	The person's consent.
25	2. The person has died and a decision of the person to consent, or not to consent, was in force immediately before the person's death.	The person's consent.
30	3. The person has died, case 2 does not apply, the person had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.
35	4. 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, but no one is able to give consent under the appointment.	Consent of a person who stood in a qualifying relationship to the person immediately before death.

- (4) But this section does not apply—
- 40 (a) if the person is an excepted adult (see section 5),
- (b) to consent for a transplantation activity that involves removal of excluded relevant material (see section 7).

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Deemed consent: deceased adults

4.—(1) Where this section applies, consent is deemed for a transplantation activity involving the body or relevant material from the body of a person.

(2) But deemed consent is only effective if—

- 5 (a) such efforts as are reasonable in the circumstances have been made to contact persons who stood in a qualifying relationship with the person immediately before death,
- (b) a person (Q) who stood in a qualifying relationship with the person immediately before death affirms that the person would not have objected to that transplantation activity, and
- 10 (c) Q has reasonable grounds for believing that the person would not have objected to that transplantation activity.

(3) This section applies if—

- (a) the person is a deceased adult, and
- 15 (b) section 3 (express consent) does not apply.

(4) But this section does not apply—

- (a) if the person is an excepted adult (see section 5),
- (b) to consent for a transplantation activity that involves removal of excluded relevant material (see section 7).

20 (5) The code of practice referred to in the Schedule makes further provision on deemed consent, affirmations and objections to affirmations.

Express consent: excepted adults

25 5.—(1) Where this section applies, express consent is required for a transplantation activity involving the body or relevant material from the body of a person.

(2) This section applies if the person is an excepted adult.

(3) An “excepted adult” means—

- 30 (a) an adult who has died and who had not been ordinarily resident in Northern Ireland for a period of at least 12 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.

35 (4) For the purposes of subsection (3)(b), a significant period means such a significantly long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given.

(5) For each case mentioned in the first column of Table 2, the meaning of express consent is set out in the second column—

TABLE 2

Case	Meaning of express consent
40 1. A decision of the excepted adult to consent, or not to consent, was in force	The excepted adult’s consent.

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	immediately before death.	
5	2. Case 1 does not apply, the excepted adult had appointed a person or persons to deal with the issue of consent and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.
10	3. Case 1 does not apply and the excepted adult had appointed a person or persons to deal with the issue of consent, 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.

15 (6) But this section does not apply to consent for a transplantation activity that involves removal of excluded relevant material (see section 7).

Express consent: children

20 **6.**—(1) Where this section applies, express consent is required for a transplantation activity involving the body or relevant material from the body of a person.

(2) This section applies where the person is a child or has died a child.

(3) For each case mentioned in the first column of Table 3, the meaning of express consent is set out in the second column—

TABLE 3

25	Case	Meaning of express consent
	1. The child is alive and case 2 does not apply.	The child's consent.
30	2. The child is alive, no decision of the child to consent, or not to consent 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.
35	3. The child has died and a decision of the child to consent, or not to consent, was in force immediately before death.	The child's consent.
40	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 and someone is able to give consent under the appointment.	Consent given by the person or persons appointed.
45	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, 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 who stood in a qualifying relationship

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	to the child at that time.
6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.	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 who stood in a qualifying relationship to the child at that time.

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(4) In this section a decision or appointment made by a child is only valid if the child was competent to deal with the issue of consent when it was made.

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(5) But this section does not apply to consent for a transplantation activity that involves removal of excluded relevant material (see section 7).

Express consent: transplantation activities involving excluded material

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7.—(1) In the case of a transplantation activity that involves the removal of excluded relevant material express consent is required, and such consent must be specific to the removal of excluded relevant material.

(2) In this Act “excluded relevant material” means relevant material of a type specified by the Department in regulations.

20

(3) Examples of the types of relevant material that may be specified are composite tissues and other types of material the removal and use of which is considered to be novel.

(4) For an adult, for each case mentioned in the first column of Table 4, the meaning of express consent is set out in the second column—

TABLE 4

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, 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 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, 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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(5) For a child, for each case mentioned in the first column of Table 5, the meaning of express consent is set out in the second column—

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TABLE 5

	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, 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, was in force immediately before death.	The child's consent.
15	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 and someone is able to give consent under the appointment.	Consent of the person or persons appointed.
20	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, 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 who stood in a qualifying relationship to the child at that time.
25	6. The child has died and none of cases 3, 4 or 5 applies in relation to the child.	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 who stood in a qualifying relationship to the child at that time.
30		

(6) In this section a decision or appointment made by a child is only valid if the child was competent to deal with the issue of consent when it was made.

Deemed consent: activities involving material from living adults who lack capacity to consent

- 35 **8.**—(1) This section applies where—
- (a) a transplantation activity involves relevant material from the body of a person (“P”) who—
 - (i) is a living 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.
- 40 (2) P’s consent to the activity is to be deemed if the activity is done in circumstances of a kind specified by regulations made by the Department.

Appointed representatives

- 45 **9.**—(1) A person may appoint one or more persons to represent the person after death in relation to express consent for the purposes of section 2.

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(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.

5 (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,

10 (b) it is signed at the direction of the person making it, in that person's presence and in the presence of at least one witness who attests the signature, or

(c) it is contained in the will of the person making it, being a will which is made in accordance with the requirements of Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994.

15 (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.

20 (8) Subsections (3) to (5) apply to the revocation of an appointment as they apply to the making of an appointment.

(9) A person appointed may at any time renounce the appointment.

(10) A person may not act under an appointment if the person—

(a) is a child, or

(b) is of a description prescribed by regulations made by the Department.

25 (11) Where a person has appointed a person or persons under—

(a) section 4 of the Human Tissue Act 2004, or

(b) section 8 of the Human Transplantation (Wales) Act 2013,

30 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.

(12) For the purposes of sections 3, 5, 6 and 7, if it is not reasonably practicable to communicate with a person appointed under this section within the time available if consent is to be acted upon, the person is to be treated as being not able to give consent to an activity under the appointment.

35 **Qualifying relationships**

10.—(1) The following are qualifying relationships for the purpose of this Act—

(a) spouse, civil partner or partner,

(b) parent or child,

(c) brother or sister,

40 (d) grandparent or grandchild,

(e) child of a brother or sister,

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- (f) stepfather or stepmother,
- (g) half brother or half sister,
- (h) friend of long standing.

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

(3) The Department may by order amend subsection (1).

(4) The code of practice referred to in the Schedule may make further provision on qualifying relationships, in particular on the ranking of qualifying relationships.

10 *Offences*

Prohibition of transplantation activities without consent

11.—(1) A person commits an offence if the person does, without consent, a transplantation activity.

(2) But a person does not commit an offence under subsection (1) if—

- 15 (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 2(3) applies, or
- (c) section 15(1) applies.

20 (3) A person (“P”) commits an offence if—

- (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
- 25 (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 to imprisonment for a term not exceeding 3 years, or to a fine, or both.

30 **Offences by bodies corporate**

12. For the purposes of this Act, section 20(2) of the Interpretation Act (Northern Ireland) 1954—

- (a) applies with the omission of the words “the liability of whose members is limited”, and
- 35 (b) (where the affairs of a body corporate are managed by its members), applies in relation to the acts or defaults of a member in connection with that member's functions of management as if that member were a director of the body corporate.

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Prosecutions

13. Proceedings for an offence under section 11 may be brought only by, or with the consent of, the Director of Public Prosecutions for Northern Ireland.

General

5 **Annual report on transplantation**

14.—(1) The Department must lay before the Assembly, in each financial year, a report about transplantation activities in that year.

(2) The report must include—

- (a) the steps taken by the Department to fulfil the duties set out in section 1,
- 10 (b) the number and nature of transplantation activities carried out in accordance with this Act.

(3) At least once every five financial years, the report must include—

- (a) the opinion of the Department as to whether this Act has been effective in promoting transplantation activities, and
- 15 (b) any recommendations the Department considers appropriate for amending the law so as to promote transplantation activities.

Preservation for transplantation

15.—(1) Where part of a body of a deceased person lying in a hospital, nursing home or other institution is or may be suitable for use for transplantation, it is
20 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—

- 25 (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
30 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.

35 (5) An act done with authority under subsection (1) is to be treated as not being an activity to which section 2 applies.

Coroners

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

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(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,

5 is, or may be, required for the purposes of functions of a coroner.

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

- (a) section 2, or
- (b) section 15,

in relation to the body or material.

10 **Relevant material**

17.—(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—

- 15 (a) embryos from outside the human body, or
- (b) hair and nail from the body of a living person.

(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).

20 *Supplementary*

Interpretation

18.—(1) In this Act—

“adult” means a person who attained the age of 18 years,

“child” means a person who has not attained the age of 18 years,

25 “Department” means the Department for Health, Social Services and Public Safety,

“qualifying relationships” has the meaning given in section 10,

“relevant material” has the meaning given in section 17; and “excluded relevant material” has the meaning given in section 7,

30 “transplantation activities” has the meaning given in section 2.

(2) In this Act 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 9.

35 (3) For the purposes of sections 6, 7 and 9 a child is competent to deal with the issue of consent if it would appear to a reasonable person that the child has sufficient understanding to make an informed decision.

(4) 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,

40 (b) references to material from the body of a deceased person are to material from the body of a person not alive at the point of separation,

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(c) references to express consent include consent given before the coming into operation of sections 3 to 10.

(5) In this Act, references to transplantation are to transplantation to a human body and include transfusion.

5 (6) 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.

Orders and regulations

10 **19.**—(1) No order or regulation under this Act may be made unless a draft of the order or regulation has been laid before, and approved by resolution of, the Assembly.

(2) Orders and regulations made under this Act may contain such incidental, consequential, supplementary, transitional and savings provisions as appear to the Department necessary or expedient.

Consequential amendments to the Human Tissue Act 2004

15 **20.** The Schedule (consequential amendments to the Human Tissue Act 2004) has effect.

Commencement

21.—(1) The following provisions come into operation 3 months after the day this Act receives Royal Assent—

- 20 (a) this section,
(b) section 1,
(c) sections 18 and 22.

(2) The other provisions of this Act come into operation on 31 May 2018.

Short title

25 **22.** This Act may be cited as the Human Transplantation Act (Northern Ireland) 2015.

SCHEDULE

Section 20.

CONSEQUENTIAL AMENDMENTS TO THE HUMAN TISSUE ACT 2004

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

5 2. In section 1 (authorisation of activities for scheduled purposes) after subsection (1) insert—

“(1ZA) Subsection (1) does not apply in relation to consent for transplantation activities (within the meaning of the Human Transplantation Act (Northern Ireland) 2015) done in Northern Ireland.”.

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

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

(b) after subsection (1) insert—

15 “(1ZA) This section does not apply in relation to transplantation activities (within the meaning of the Human Transplantation Act (Northern Ireland) 2015) done in Northern Ireland.

(For provision in these circumstances see section 8 of the Human Transplantation Act (Northern Ireland) 2015).”.

20 4. In section 8 (restriction of activities in relation to donated material), in subsection (6) after “section 1(1) to (3)” insert “or section 2 of the Human Transplantation Act (Northern Ireland) 2015”.

5. In section 15 (general functions of the Human Tissue Authority) in paragraph (c)(i) after “this Part” insert “or under the Human Transplantation Act (Northern Ireland) 2015”.

25 6. In section 26 (preparation of codes)—

(a) in subsection (2)(d) after “this Act” insert “and the Human Transplantation Act (Northern Ireland) 2015”,

(b) in subsection (3) after “deal with consent” insert “(including consent for the purposes of the Human Transplantation Act (Northern Ireland) 2015)”.

30 7. In section 27 (provisions with respect to consent)—

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

(b) after subsection (1) insert—

“(1ZA) Those provisions are—

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

(b) section 3, 5, 6 or 7 of the Human Transplantation Act (Northern Ireland) 2015.”,

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

40 (d) after subsection (8) insert—

“(8C) 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 of the Human Transplantation Act (Northern Ireland) 2015 (deemed consent: deceased adults).

(8D) In giving practical guidance on the circumstances in which consent is deemed, the Authority must, in particular, give guidance on—

- 5 (a) how a person in a qualifying relationship can give an affirmation,
 (b) how a person in a qualifying relationship can object to an affirmation, and
 (c) the procedure to be followed where there is both an affirmation and an objection to an affirmation.”,

10 (e) in subsection (9) after “subsection (4)” insert “except in so far as it applies to section 3, 5, 6 or 7 of the Human Transplantation Act (Northern Ireland) 2015”,

(f) after subsection (9) insert—

15 “(9A) The relevant Northern Ireland department may by order amend subsection (4) in so far as it applies to section 3, 5, 6 or 7 of the Human Transplantation Act (Northern Ireland) 2015.

 (9B) Before making an order under subsection (9A) the relevant Northern Ireland department must carry out such public consultation as the department considers appropriate.”.

20 8. In section 29 (approval of codes)—

(a) after subsection (1) insert—

25 “(1ZA) Where a code of practice to which subsection (1) applies deals with a matter relating to the carrying on in Northern Ireland of a transplantation activity (within the meaning of the Human Transplantation Act (Northern Ireland) 2015) the Authority may not issue the code unless—

 (a) a draft of it has been sent to and approved by the relevant Northern Ireland department and laid by that department before the Northern Ireland Assembly, and

30 (b) the Northern Ireland Assembly has approved the draft by resolution.”,

(b) after subsection (4) insert—

35 “(4ZA) If the relevant Northern Ireland department does not approve a draft sent under subsection (1ZA), the department shall give reasons to the Authority.”.

9. In section 43 (preservation for transplantation) after subsection (6) insert—

 “(6A) This section does not apply in relation to a part of a body lying in an institution in Northern Ireland.

40 (For provision in these circumstances see section 15 of the Human Transplantation Act (Northern Ireland) 2015).”.

10. In section 52 (orders and regulations) after section (4) insert—

 “(4ZA) No order under section 27(9A) may be made by the relevant Northern Ireland department unless a draft of the instrument has been laid before and approved by a resolution of the Northern Ireland Assembly.”.

45 11. In Schedule 4 (section 45: supplementary) after paragraph 11 insert—

*“Purpose authorised under section 2 of the Human Transplantation Act
(Northern Ireland) 2015*

5 11A. Use of the results of an analysis of DNA for a purpose specified in
paragraph 7 is use for an excepted purpose if the use in Northern Ireland
for that purpose of the bodily material concerned is authorised by section 2
of the Human Transplantation Act (Northern Ireland) 2015.”.

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
Act (Northern Ireland) 2015”,
- 10 (b) in paragraph 5(2) after “2” insert “or under the Human Transplantation Act
(Northern Ireland) 2015”.

Human Transplantation Bill

[AS INTRODUCED]

A Bill 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.

Introduced by: Mrs Jo-Anne Dobson

On: 13 October 2015

Bill Type: Non-Executive Bill

ACCOMPANYING DOCUMENTS

**An Explanatory and Financial Memorandum is printed separately as
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