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Explanatory Memorandum](#)

**AN BILLE UM ORGÁIN DE CHUID CHORP AN DUINE
AGUS FÍOCHÁIN DHAONNA 2008**
HUMAN BODY ORGANS AND HUMAN TISSUE BILL 2008

Mar a tionscnaíodh
As initiated

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[No. 43 of 2008]

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AN BILLE UM ORGÁIN DE CHUID CHORP AN DUINE
AGUS FÍOCHÁIN DHAONNA 2008
HUMAN BODY ORGANS AND HUMAN TISSUE BILL 2008

BILL

5 *entitled*

AN ACT TO REGULATE THE REMOVAL, STORAGE AND
USE OF HUMAN BODY ORGANS AND HUMAN TISSUE
FOR CERTAIN PURPOSES, TO REGULATE CONSENTS
IN RELATION THERETO AND TO PROVIDE FOR CER-
10 TAIN OTHER RELATED MATTERS.

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

1.—This Act may be cited as the Human Body Organs and Human Tissue Act 2008. Short title.

2.—In this Act, the following expressions shall have the meanings
15 attributed to them: Interpretation.

“excepted material” means material which has—

- (a) come from the body of a living person, or
- (b) come from the body of a deceased person otherwise than
20 in the course of use of the body for the purpose of ana-
tomical examination;

“permitted activities” means the activities set forth in *section 4(1)*;

“relevant person” means a person (and, where the context so admits
or requires, may include a deceased person) in respect of whose
human body organs and human tissue the provisions of this Act
25 apply;

“scheduled purposes” means the purposes set forth in the *Schedule*
and in *section 12(3)*; and

“the Minister” means the Minister for Health and Children.

3.—(1) Save as otherwise provided in this Act (or in any other
30 enactment) all persons shall be deemed, unless they have withheld
consent or are deemed to have so withheld consent in accordance
with the provisions of this Act, to have consented to permitted activi-
ties for scheduled purposes as set out in the *Schedule* to this Act. Consent.

Subject to the provisions of this Act, there shall be a general presumption that relevant persons shall be deemed to have consented to permitted activities being conducted by registered medical practitioners or persons under their direction and supervision or such other persons or classes of persons as the Minister may, by order, specify for this purpose as being authorised for the purpose. 5

(2) The withholding of consent for purposes of *section 3* shall only be validly effected in the following circumstances:

- (a) where the relevant person has been deemed to have withheld consent in accordance with *sections 5* or *6* of this Act or through his or her nominated representative in accordance with *section 8* of this Act; 10
- (b) where a nominated representative has withheld consent on behalf of a relevant person in accordance with *section 8* of this Act and such withholding of consent has not been revoked and such withholding is known at a material time to a registered medical practitioner or other person authorised pursuant to the provisions of this Act to undertake permitted activities or other persons relying on such consent for purposes of the subject-matter of this Act; or 15 20
- (c) by a relevant person exhibiting on his or her person or clothing or personal possessions or effects or by having made an entry on any website or other public place for the time being approved for this purpose by order made by the Minister or otherwise making known, directly or indirectly, to a registered medical practitioner or other person for the time being authorised to engage in permitted activities the fact of the withholding of the consent of such relevant person to such permitted activities. 25

Permitted activities.

4.—(1) The following activities (in this Act called “permitted activities”) in connection with the removal, storage and use of human body organs and human tissue for scheduled purposes shall be lawful as being deemed to be within the scope of the consent of a relevant person provided that such relevant person (including, where the context so admits or requires, a deceased person) shall not have withheld (or be deemed to have so withheld) his or her consent in accordance with the provisions of this Act: 30 35

- (a) the storage of the body of a deceased person for use for a purpose specified in the *Schedule*, other than an anatomical examination; 40
- (b) the use of the body of a deceased person for a purpose specified in the *Schedule*, other than an anatomical examination;
- (c) the removal from the body of a deceased person, for use for a purpose specified in the *Schedule*, of any material of which the body consists or which it contains; 45
- (d) the storage for use for a purpose specified in *Part 1* of the *Schedule* of any relevant material which has come from a human body;
- (e) the storage for use for a purpose specified in *Part 2* of the *Schedule* of any relevant material which has come from the body of a deceased person; 50

- (f) the use for a purpose specified in *Part 1* of the *Schedule* of any relevant material which has come from a human body; or
- 5 (g) the use for a purpose specified in *Part 2* of the *Schedule* of any relevant material which has come from the body of a deceased person.
- (2) The storage of the body of a deceased person for use for the purpose of anatomical examination shall be lawful as being within the scope of the consent of a relevant person if—
- 10 (a) appropriate consent has not been withheld in accordance with the provisions of this Act, and
- (b) it is after the signing of a certificate of death pursuant to section 13(4) of the Civil Registration Act 2004 of the cause of death of the person.
- 15 (3) The use of the body of a deceased person for the purpose of anatomical examination shall be lawful as being within the scope of the consent of a relevant person—
- (a) if appropriate consent has not been withheld by a relevant person in accordance with the provisions of the Act, and
- 20 (b) after the death of the person has been registered in accordance with the Civil Registration Act 2004.
- (4) *Subsections (1) to (3)* do not apply to an activity of a kind mentioned therein if it is done in relation to—
- (a) a body to which *subsection (5)* applies, or
- 25 (b) relevant material to which *subsection (6)* applies.
- (5) This subsection applies to a body if—
- (a) it has been imported from outside the State, or
- (b) it is the body of a person who died before the day on which this Act comes into force and at least 100 years have elapsed since the date of the person's death.
- 30 (6) This subsection applies to relevant material if—
- (a) it has been imported from outside the State,
- (b) it has come from a body which has been imported from outside the State, or
- 35 (c) it is material which has come from the body of a person who died before the day on which this Act comes into force and at least 100 years have elapsed since the date of the person's death.
- (7) *Subsection (1)(d)* does not apply to the storage of relevant material for use for the purpose of research in connection with disorders, or the functioning, of the human body unless—
- 40 (a) the material has come from the body of a living person, and

(b) the research falls within *subsection (9)*.

(8) *Subsection (1)(f)* does not apply to the use of relevant material for the purpose of research in connection with disorders, or the functioning, of the human body unless—

(a) the materials come from the body of a living person, and 5

(b) the research falls within *subsection (9)*.

(9) Research falls within this subsection if—

(a) it is conducted in accordance with proper principles and good practice, or in accordance with any legislation for the time being, governing such research by, or under the direct supervision of, registered medical practitioners or other persons for the time being so authorised in accordance with the provisions of this Act, and 10

(b) it is to be, or is, carried out in circumstances such that the person carrying it out is not in possession and not likely to come into possession, of information from which the person from whose body the material has come can be identified. 15

(10) The following activities shall be lawful as being within the scope of the consent of a relevant person: 20

(a) the storage for use for a purpose specified in *Part 2* of the *Schedule* which has come from the body of a living person;

(b) the use for such purpose of any relevant material which has come from the body of a living person; or 25

(c) an activity in relation to which *subsections (4), (7) or (8)* has effect.

(11) The Minister may by order made pursuant to this subsection amend or revoke in whole or in part the terms of the *Schedule*.

(12) Nothing in this section applies to— 30

(a) the use of relevant material in connection with a device to which Directive 98/79/EC of the European Parliament of the Council on *in vitro* diagnostic medical devices applies, where the use falls within the Directive, or

(b) the storage of relevant material for use falling within *paragraph (a)*. 35

(13) In this section, the references to a body or material which has been imported from outside the State do not include a body or material which has been imported from outside the State after having been exported with a view to its subsequently being re-imported. 40

Withholding of consent in relation to children.

5.—(1) This section makes provision for the interpretation of withholding of consent in *section 4* in relation to an activity involving the body, or material from the body, of a person who is a child (that is without having reached his or her age of majority) or has died a child (“the child concerned”). 45

(2) Subject to *subsection (3)*, where the child concerned is alive, consent being withheld means the consent of the child concerned being withheld.

(3) Where—

- 5 (a) the child concerned is alive,
- (b) neither a decision of the child concerned to consent to the activity nor a decision of the child concerned not to consent to it, is in force, and
- 10 (c) either the child concerned is not competent to deal with the issue of consent in relation to the activity or, though he or she is competent to deal with that issue, he or she fails to do so,

withholding of consent refers to withholding of consent by a person who has parental responsibility for the child concerned.

- 15 (4) Where the child concerned has died and the activity is one to which *subsection (5)* applies, withholding of consent means that withholding of consent in writing.

(5) This subsection applies to activity involving storage for use, or use, for the purpose of—

- 20 (a) public display, or
- (b) where the subject matter of this activity is not excepted material, anatomical examination.

(6) Withholding of consent in writing for the purposes of *subsection (4)* shall only be valid if—

- 25 (a) it is signed by the child concerned in the presence of at least one witness who attests the signature, or
- (b) it is signed by direction of the child concerned, in his or her presence and in the presence of at least one witness who attests the signature.

- 30 (7) Where the child concerned has died and the activity is not one to which *subsection (5)* applies, withholding of consent means—

- (a) if a decision of the child concerned to withhold consent to the activity, or a decision of the child concerned not to consent, was in force immediately before he or she died, his or her withholding of consent, and
- 35 (b) if *paragraph (a)* does not apply—

- (i) the withholding of consent of a person who had parental responsibility for the child concerned immediately before he or she died, or
- 40 (ii) where no person had parental responsibility for the child concerned immediately before he or she died,

the withholding of consent by a person who stood in a qualifying relationship to the child concerned at that time.

6.—(1) This section makes provision for the interpretation of withholding of consent in *section 8* in relation to activity involving the body, or material from the body, of a person who is an adult or has died an adult (“the person concerned”) and, for this purpose, an adult shall be a person who has reached the age of majority. 5

(2) Where the person concerned is alive, withholding of consent means the withholding of his or her consent.

(3) Where the person concerned has died and the activity is one to which *subsection (4)* applies, withholding of consent means withholding of his or her consent in writing and in accordance with *section 3(2)*. 10

(4) This subsection applies to an activity involving storage for use, or use, for the purpose of—

(a) public display, or

(b) where the subject matter of the activity is not excepted material, anatomical examination. 15

(5) Withholding of consent in writing for the purposes of *subsection (3)* shall only be valid if—

(a) it is signed by the person concerned in the presence of at least one witness who attests the signature, 20

(b) it is signed at the direction of the person concerned, 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 concerned made in accordance with the requirements of the Succession Act 1965. 25

(6) Where the person concerned has died and the activity is not one to which *subsection (4)* applies, withholding of consent means—

(a) if a decision of the person concerned to withhold the consent to the activity, or a decision of the person concerned not to consent to it, was in force immediately before the person died the withholding of his or her consent, or 30

(b) if—

(i) *paragraph (a)* does not apply, and

(ii) he or she has appointed a person or persons under *section 8* to deal after his or her death with the issue of withholding of consent in relation to the activity, 35

withholding of consent given under the appointment, or

(c) if neither *paragraph (a)* nor *paragraph (b)* applies,

the withholding of consent of a person in a qualifying relationship to the person concerned immediately before he or she died. 40

(7) Where the person concerned has appointed a person or persons under *section 8* to deal after his or her death with the issue of

consent in relation to the activity, the appointment shall be disregarded for the purposes of *subsection (6)* if no one is able to issue withholding of consent under it.

5 (8) If it is not reasonably practicable to communicate with the person appointed under *section 8* within the time available if withholding of consent might be in doubt, the person concerned shall be treated with reference to *subsection (7)* as not able to withhold consent under the appointment in relation to it.

10 7.—(1) The qualifying relationships for the purpose of *section 5(7)(b)(ii)* and *section 6(6)(c)* shall be ranked in the following order: Qualifying relationships.

(a) spouse;

(b) parent or child;

(c) brother or sister;

(d) grandparent or grandchild;

15 (e) child of a person falling within *paragraph (c)*;

(f) stepfather or stepmother;

(g) half-brother or half-sister; and

(h) friend of longstanding.

20 (2) Relationships in the same paragraph of *subsection (1)* should be accorded equal ranking.

(3) Withholding of consent should have been received from the person whose relationship to the person concerned is accorded the highest ranking in accordance with *subsections (1)* and *(2)*.

25 (4) If the relationship of each of two or more persons to the person concerned is accorded equal highest ranking in accordance with *subsections (1)* and *(2)*, it is sufficient that withholding of consent shall have been received from any of them.

(5) In applying the principles set out above, the person's relationship shall be left out of account if—

30 (a) he or she does not wish to deal with the issue of consent,

(b) he or she is not able to deal with that issue, or

35 (c) having regard to the activity in relation to which withholding of consent might have been obtained, it is not reasonably practicable to communicate with him or her within the time available if withholding of consent in relation to the activity is to be acted on.

8.—(1) An adult may appoint one or more persons to represent him or her after his or her death in relation to withholding of consent for the purposes of *section 4*. Nominated representatives.

40 (2) An appointment under this section may be general or limited to withholding of consent in relation to such one or more activities as may be specified in the appointment.

(3) An appointment under this section may be made orally or in writing.

(4) An oral appointment under this section is only valid if made in the presence of at least two witnesses present at the same time.

(5) A written appointment under this section is only valid if— 5

(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 10

(c) it is contained in a will of the person making it, being a will which is made in accordance with the requirements of the Succession Act 1965.

(6) Where a person appoints two or more persons under this section in relation to the same activity, they should be regarded as appointed to act jointly and severally unless the appointment provides that they are appointed to act jointly. 15

(7) An appointment under this section may be revoked at any time.

(8) *Subsections (3) to (5)* apply to the revocation of an appointment under this section as they apply to the making of such an appointment. 20

(9) A person appointed under this section may at any time renounce his or her appointment.

(10) A person may not act under an appointment under this section if— 25

(a) he or she is not an adult, or

(b) he or she is of a description prescribed for the purposes of this provision by order made by the Minister.

Activities without consent.

9.—(1) A person shall be deemed as acting outside the terms of the consent of a relevant person if, without further consent, he or she engages in an activity to which *subsections (1), (2) and (3) of section 4* apply unless he or she reasonably believes— 30

(a) that he or she is doing or engaging in an activity within the terms of a consent, or 35

(b) that what he or she does or is engaging in is not an activity to which this subsection applies.

(2) A person acts other than in accordance with the consent if—

(a) he or she falsely represents to a person whom he or she knows or believes is going to, or may, engage in an activity to which *subsections (1), (2) and (3) of section 4* apply— 40

(i) that there is consent to the doing of, or engagement in, the activity, or

(ii) that the activity is not one to which the subsection applies,

and

(b) he or she knows that the representation is false or does not believe it to be true.

(3) Subject to *subsection (4)*, a person shall be liable in civil law if he or she does, or engages in, an activity to which *section 4(2)* applies, where in relation to the cause of death of the person concerned, a certificate of death under the provisions of the Civil Registration Act 2004 has not been signed.

(4) *Subsection (3)* does not apply—

(a) where the person reasonably believes,

(i) that such a certificate has been signed in relation to the cause of death of the person concerned, or

(ii) that what he or she does, or engages in, is not an activity to which *section 4(2)* applies,

or

(b) where the person comes into lawful possession of the body immediately after death and stores it prior to its removal to a place where anatomical examination is to take place.

(5) Subject to *subsection (6)*, a person shall be liable in civil law if, when he or she does, or engages in, an activity to which *section 4(3)* applies, the death of the person concerned has not been registered under the provisions of the Civil Registration Act 2004.

(6) *Subsection (5)* does not apply where the person reasonably believes—

(a) that the death of the person concerned has been registered under such provisions, or

(b) that what he or she does, or engages in, is not an activity to which *section 4(3)* applies.

(7) In this section “consent” and “withholding of consent” have the meanings used in this Act including in *section 3*.

10.—Where—

(a) an activity of the kind mentioned in *section 4(1)(d)* or (f) involves material from the body of a person who—

(i) is an adult, and

(ii) lacks capacity to withhold consent to the activity,

and

(b) neither a decision of his or her to withhold consent to the activity, nor a decision of his or her to consent to it is in force,

Activities involving material from adults who lack capacity to consent.

there shall, for the purposes of this Act, be deemed to be consent of his or her to the activity if it is done in circumstances of the kind specified by Regulations made by the Minister.

Applications to the Court.

11.—(1) The High Court, if it sees fit, may make such order as it deems appropriate in relation to this Act.

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(2) Without prejudice to the generality of the foregoing, the Court may give directions, dispense with the need for consent, declare that consent has been withheld or deemed to have been withheld or given or deemed given or declare that such consent or withholding has been given or deemed given in whole or in part or subject to such conditions as to the Court seem proper.

10

(3) Without prejudice to the generality of the foregoing, if the Court is satisfied that—

(a) relevant material has come from the body of a living person,

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(b) it is not reasonably possible to trace the person from whose body the material has come (“the donor”),

(c) it is desirable in the interests of another person (including a future person) that the material be used for the purpose of obtaining scientific or medical information about the donor,

20

(d) there is no reason to believe—

(i) that the donor has died,

(ii) that a decision of the donor to withhold consent to the use of material for that purpose is in force, or

25

(iii) that the donor lacks capacity to consent or withhold consent to the use of material for that purpose,

the Court may direct that *subsection (5)* apply to the material for the benefit of the other person.

(4) If the Court is satisfied that—

30

(a) relevant material has come from the body of a living person,

(b) it is desirable in the interests of another person (including a future person) that the material be used for the purpose of obtaining scientific or medical information about the donor,

35

(c) reasonable efforts have been made to get the donor to decide whether to withhold consent or to consent to the use of the material for that purpose,

(d) there is no reason to believe—

40

(i) that the donor has died,

(ii) that the decision of the donor to refuse or consent to the use of the material for that purpose is in force, or

- (iii) that the donor lacks capacity to consent to the use of the material for that purpose,

and

- (e) the donor has been given notice of the application for the exercise of the power conferred by this subsection,

the Court may direct that *subsection (5)* applies to materials for the benefit of the other person.

(5) Where material is a subject of direction under *subsection (3)* or *(4)*, there shall for the purposes of this Act be deemed to be consent of the donor to the use of the material for the purpose of obtaining scientific or medical information about him or her which may be relevant to the person for whose benefit the decision is given.

(6) The Court may make an order deeming that, for the purposes of this Act, there would be consent to an activity consisting of—

- (a) the storage of a body of a deceased person for use for the purpose of research in connection with disorders, or the functioning, of the human body,

- (b) the use of the body of a deceased person for that purpose,

- (c) the removal from the body of a deceased person, for use for that purpose, of any relevant material of which the body consists or which it contains,

- (d) the storage for use for that purpose of any relevant material which has come from the human body, or

- (e) the use for that purpose of any relevant material which has come from a human body.

12.—(1) Subject to *subsection (2)*, a person shall be liable in civil law if he or she—

Restriction of activities in relation to donated material.

- (a) uses donated material for a purpose which is not a scheduled purpose, or

- (b) stores donated material for use for a purpose which is not a scheduled purpose.

(2) *Subsection (1)* does not apply where the person reasonably believes that what he or she uses, or stores, is not donated material.

(3) In *subsection (1)* references to a scheduled purpose are to—

- (a) a purpose specified in the *Schedule*,

- (b) the purpose of medical diagnosis or treatment, and

- (c) the purpose of decent disposal, and

- (d) a purpose specified in Regulations made by the Minister.

(4) In this section, references to donated material are to—

- (a) the body of a deceased person, or

(b) relevant material which has come from a human body,

which is, or has been, the subject of donation.

(5) For the purposes of *subsection (4)*, a body, or material, is the subject of donation if consent under *section 4(1) to (3)* exists in relation to it.

5

Existing holdings.

13.—(1) In its application to the following activities, *section 4(1)* shall be deemed to have effect with the benefit of consent in relation to—

(a) the storage of an existing holding for use for a scheduled purpose,

10

(b) the use of an existing holding for a scheduled purpose.

(2) *Subsection (1)* does not apply where the existing holding is a body or separate part of a body, in relation to which *section 14(3) or (5)* has effect.

(3) *Section 9(1) and (2)* shall have effect as if the activities mentioned in *subsection (1)* are not activities to which *section 4(1)* applies.

15

(4) In this section, “existing holding” means—

(a) the body of a deceased person, or

(b) relevant material which has come from a human body,

20

held, immediately before the day on which this Act comes into force, for use for a purpose specified in the *Schedule*.

Existing anatomical specimens.

14.—(1) This section applies where a person dies during the three years immediately preceding the coming into force of *section 4*.

(2) *Subsection (3)* applies where—

25

(a) before this Act comes into force, authority is given under any applicable ethical code for a person’s body to be used for anatomical examination, and

(b) this Act comes into force before an anatomical examination of the person’s body is concluded.

30

(3) During so much of the relevant period after this Act comes into force, that consent shall be treated for the purpose of *section 4* as consent in relation to—

(a) the storage of the person’s body, or separated parts of his or her body, for use for the purpose of anatomical examination, and

35

(b) the use of his or her body, or separated parts of his or her body, for that purpose.

(4) *Subsection (5)* applies where—

(a) before this Act comes into force, authority is given under any applicable ethical or other codes for possession of

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parts (or any specified parts) of the person's body to be held after anatomical examination of his or her body is concluded, and

5 (b) anatomical examination of the person's body is concluded after this Act comes into force, but before the end of the period of three years beginning with the date of the person's death.

10 (5) With effect from the conclusion of the anatomical examination of the person's body, that authority or consent should be treated for the purpose of *section 4* as consent in relation to—

(a) the storage for use for a scheduled purpose of a part of the person's body which—

(i) is a part to which that authority or consent relates, and

15 (ii) is such that the relevant person shall not be recognised simply by examination of the part,

and

(b) the use for a scheduled purpose of such a part of the person's body.

20 (6) Where for the purposes of *section 4*, there would not be consent in relation to authority under any such ethical code shall be treated for those purposes as consent in relation to the activity, *section 4(1)* to (3) does not authorise the doing, or engaging, in the activity otherwise than in accordance with that authority or consent.

25 (7) In *subsection (3)* the “relevant period” in relation to a person, means whichever is the shorter of—

(a) the period of 3 years beginning with the date of the person's death, and

30 (b) the period beginning with that date and ending when an anatomical examination of the person's body is concluded.

15.—(1) Nothing in this Act applies to anything done for purposes of functions of a coroner or under the authority of a coroner within the meaning of the Coroners Acts 1962 to 2005. Coroners.

35 (2) Where a person 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,

40 he or she shall not act on authority under *section 4* in relation to the body, or material, except with the consent of the coroner.

16.—A person liable in civil law under this Act shall be liable to be sued in a court of competent jurisdiction and to be held liable in monetary damages, to injunctive relief or such other remedy as the court sees fit as if the person had been held liable in tort.

SCHEDULE

SCHEDULE PURPOSES

PART 1

PURPOSES REQUIRING CONSENT AND WHERE CONSENT PRESUMED GIVEN SAVE IN ACCORDANCE WITH THIS ACT: GENERAL

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2. Determining the cause of death.
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4. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person 15
(including a future person).
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6. Research in connection with disorders, or the functioning, of the human body.
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PART 2

PURPOSES REQUIRING CONSENT AND WHERE CONSENT PRESUMED GIVEN SAVE IN ACCORDANCE WITH THIS ACT: DECEASED PERSONS

1. Clinical audit.
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3. Performance assessment.
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**AN BILLE UM ORGÁIN DE CHUID CHORP AN DUINE
AGUS FÍOCHÁIN DHAONNA 2008**

HUMAN BODY ORGANS AND HUMAN TISSUE BILL 2008

EXPLANATORY AND FINANCIAL MEMORANDUM

The main purpose of this Bill is to provide for a presumption in favour of consent by persons to the undertaking of certain activities in relation to their bodies for purposes of removal of human body organs and human tissue for certain purposes as specified in the Bill. It is intended to provide in general for a presumption in favour of consent having been given unless it is expressly withheld. The Bill further makes provision for related matters including as to the consent, activities permitted to be undertaken by a registered medical practitioner or other persons under their supervision and for related matters.

Section 1 sets forth the short title and is standard.

Section 2 contains certain definitions and interpretations and is standard.

Section 3 provides in detail for consents and matters relating thereto. This Section provides that unless persons have withheld consent or are deemed to have so withheld consent in accordance with the Act they are deemed to have consented to the “permitted activities” for “scheduled purposes” set out in the Schedule to the Act. These activities and scheduled purposes include the harvesting of organs and the taking of body tissue under appropriate circumstances. The Section further provides for this to be undertaken under the direction and supervision of registered medical practitioners or persons under their direction and supervision and such other persons or classes of persons as to the Minister may, by order, specify for the purpose.

Section 4 together with the Schedule provide for permitted activities. These set out in detail permitted activities in connection with the removal, storage and use of human body organs and human tissue for scheduled purposes. The Section extends also to provide for the storage of the bodies of deceased persons and for the use of the body of a deceased person for purposes of anatomical examination.

Section 5 makes further provision for withholding of consent in relation to children. This Section attempts to recognise vulnerabilities of children while at the same time striking the appropriate balance to ensure the availability of human body organs and human

tissue. The Section also extends to the storage for use or the use of a body for public display and for anatomical examination. There is also provision in relation to consent in relation to a deceased child.

Section 6 makes more detailed provision for withholding of consent in relation to adults. This contains provision in relation to adults for circumstances in which consent is deemed to be withheld and otherwise generally contains provisions similar to those in respect of children.

Section 7 provides for qualifying relationships in the context of withholding of consent in relation to children and adults.

Section 8 provides for nominated representatives who would represent an appointor after the death of the appointor. The Section reflects modern practice in respect of a person making provision for dealing with his or her affairs including by testamentary disposition. The Section provides for the appointment of nominated representatives and related matters in connection therewith including revocation of appointment.

Section 9 provides for certain activities not being within the terms of consent. The sanction for exceeding the terms of the consent is specified purely in terms of civil liability. It would ordinarily be in the nature of a tort (civil wrong) and with appropriate remedies available in the Courts. The Bill does not attempt to make provision for penalties in Criminal Law. The sanction herein specified may be read in conjunction with Section 16 (Civil Liability).

Section 10 provides for activities involving material from adults who lack capacity to consent. There is provision for the deeming of consent to be in place although there is also authority for the Minister to make fuller provision by regulations.

Section 11 provides for restriction of activities in relation to donated material. This Section provides for application to the High Court which empowers the Court to make a wide range of orders. It is accorded a general discretion in wide terms. This must in any case be set against the full original jurisdiction bestowed upon the High Court under the Constitution of Ireland. In addition to that, there is a wide range of specific powers also proposed to be accorded to the Court without prejudice to the generality of its powers.

Section 12 provides for restriction of activities in relation to donated materials. Again, the sanction for transgression here is liability in civil law. This Section must also be read in conjunction with Section 16 on Civil Liability.

Section 13 provides for existing holdings of materials.

Section 14 deals with existing anatomical specimens.

Section 15 saves activities undertaken as functions of a coroner or under the authority of a coroner. These are not covered by the Bill.

Section 16 provides for remedies for liability in civil law. This is effectively akin to liability in tort (matters such as trespass, negligence, nuisance and so forth) and in ordinary course the Courts would have a wide discretion to award damages, grant injunctive relief or such other remedy as might be appropriate in the circumstances. Provision is so made in this case.

The Bill is not expected to give rise to additional Exchequer expenditure. Furthermore, the Bill is not expected to have any material regulatory impact upon activities in the State.

*Senator Feargal Quinn,
September 2008.*