



**Isle of Man**

*Ellan Vannin*

**AT 13 of 2021**

**HUMAN TISSUE AND ORGAN  
DONATION ACT 2021**





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## HUMAN TISSUE AND ORGAN DONATION ACT 2021

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## HUMAN TISSUE AND ORGAN DONATION ACT 2021

*Signed in Tynwald:* 20 July 2021  
*Received Royal Assent:* 20 July 2021  
*Announced to Tynwald:* 20 July 2021

**AN ACT** to make provision about activities involving human tissue and the donation of human organs; and for connected purposes.

**BE IT ENACTED** by the Queen’s Most Excellent Majesty, by and with the advice and consent of the Council and Keys in Tynwald assembled, and by the authority of the same, as follows:—

### PART 1 – INTRODUCTORY

#### **1 Short title**

The short title of this Act is the Human Tissue and Organ Donation Act 2021.

#### **2 Commencement**

- (1) This Act comes into operation on such day or days as the Department may by order appoint.
- (2) An order under subsection (1) may include such consequential, incidental, supplementary transitional and transitory provision as appear to the Department to be appropriate.

#### **3 Interpretation**

P2004/30/54 and drafting

- (1) In this Act —  
“**the 2004 Act**” means the Human Tissue Act 2004 (of Parliament)<sup>1</sup>,

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<sup>1</sup> 2004 c. 30.

“**the 2007 Regulations**” means the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (of Parliament)<sup>2</sup>, and

“**the 2012 Regulations**” means the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (of Parliament)<sup>3</sup>,

in each case as that Act or those Regulations have effect in England, but subject to any modification provided for in an order under section 71.

(2) In this Act—

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

“**anatomical examination**” means macroscopic examination by dissection for anatomical purposes;

“**anatomical purposes**” means purposes of teaching or studying, or researching into, the gross structure of the human body;

“**anatomical specimen**” means—

- (a) the body of a deceased person to be used for the purpose of anatomical examination, or
- (b) the body of a deceased person in the course of being used for the purpose of anatomical examination (including separated parts of such a body);”

“**appropriate consent**” is to be construed by reference to section 8 or 9 (as the case requires);

“**child**”, except in the context of qualifying relationships, means a person who has not attained the age of 18 years;

“**Coroner**” means the High Bailiff acting as the coroner of inquests and includes any deputy coroner or acting coroner appointed under section 1(2) of the *Coroner of Inquests Act 1987*;

“**the Department**” means the Cabinet Office;

“**DHSC**” means the Department of Health and Social Care;

“**designated individual**” shall be construed in accordance with section 22;

“**licence**” means a licence under paragraph 1 of Schedule 2;

“**licensed activity**”, in relation to a licence, means the activity which the licence authorises to be carried on;

“**NHSBT**” means the Special Health Authority known as NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG)<sup>4</sup>;

“**organ**” means an organ of the human body;

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<sup>2</sup> SI 2007/1523

<sup>3</sup> S.I. 2012/1501

<sup>4</sup> See S.I. 2005/2529.



“**parental responsibility**” is to be construed in accordance with the *Children and Young Persons Act 2001*;

“**qualifying relationship**” is to be construed in accordance with section 5;

“**scheduled purposes**” are purposes specified in Schedule 1; and

“**tissue**” and “**tissue sample**” are to be construed in accordance with section 4.

- (3) 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, and
  - (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.
- (4) In this Act, references to transplantation are to transplantation to a human body and include transfusion.
- (5) In this Act, references to decent disposal include, in relation to disposal of an organ or tissue which has (in either case) come from a human body, disposal as clinical waste.
- (6) In this Act, references to public display, in relation to the body of a deceased person, do not include —
- (a) display for the purpose of enabling people to pay their final respects to the deceased, or
  - (b) display which is incidental to the deceased’s funeral.
- (7) In this Act “**embryo**” and “**gametes**” have the same meaning as they have in England and Wales by virtue of section 1(1), (4) and (6) of the Human Fertilisation and Embryology Act 1990 (of Parliament)<sup>5</sup> in the other provisions of that Act (apart from section 4A)<sup>6</sup>.
- (8) For the purposes of this Act, an organ or tissue shall not be regarded as from a human body if it is created outside the human body.

#### 4 References to tissue and tissue sample

Drafting, but see S2006/asp4/60.

In this Act —

- (a) references to “**tissue**” from a human body include skin, a cornea and bone marrow, but do not include —
  - (i) embryos outside the human body, or
  - (ii) hair and nail from the body of a living person; and

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<sup>5</sup> 1990 c. 37.

<sup>6</sup> Section 4A was inserted by section 4(2) of the Human Fertilisation and Embryology Act 2008 (of Parliament) (2008 c. 22).

- (b) references to “**tissue sample**” include anything derived from skin.

## 5 **Persons in a qualifying relationship with another**

- (1) For the purposes of this Act a “**qualifying relationship**” is a relationship of any of the following descriptions—
- (a) spouse, civil partner or partner;
  - (b) parent or child;
  - (c) brother or sister;
  - (d) grandparent or grandchild;
  - (e) child of a person falling within paragraph (c);
  - (f) stepfather or stepmother;
  - (g) half-brother or half-sister;
  - (h) friend of longstanding.
- (2) Qualifying relationships are to be ranked in the order in which they are listed in subsection (1), but relationships mentioned in the same paragraph of that subsection are to be accorded equal ranking.
- (3) Consent should be obtained from the person whose relationship to the person concerned is accorded the highest ranking in accordance with subsections (1) and (2).
- (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 to obtain the consent of any of them.
- (5) In applying the principles set out above, the relationship of a person (“P”) is to be left out of account if —
- (a) P does not wish to deal with the issue of consent,
  - (b) P is not able to deal with that issue, or
  - (c) having regard to the activity in relation to which consent is sought, it is not reasonably practicable to communicate with P within the time available if consent in relation to the activity is to be acted on.
- (6) 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.
- (7) The Department may by order amend subsection (6).

## PART 2 — REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

### 6 Interpretation of Part 2

P2004/30/12

In this Part, “**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 in the course of use of the body for the purpose of anatomical examination.

### 7 Authorisation of activities for scheduled purposes

P2004/30/1

- (1) The following activities are lawful if done with appropriate consent —
  - (a) the storage of the body of a deceased person for use for a purpose specified in Schedule 1, other than anatomical examination;
  - (b) the use of the body of a deceased person for a purpose so specified, other than anatomical examination;
  - (c) the removal from the body of a deceased person, for use for a purpose specified in Schedule 1, of any organ or tissue of which the body consists or which it contains;
  - (d) the storage for use for a purpose specified in Part 1 of Schedule 1 of any organ or tissue which has come from a human body;
  - (e) the storage for use for a purpose specified in Part 2 of Schedule 1 of any organ or tissue which has come from the body of a deceased person;
  - (f) the use for a purpose specified in Part 1 of Schedule 1 of any organ or tissue which has come from a human body;
  - (g) the use for a purpose specified in Part 2 of Schedule 1 of any organ or tissue 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 if done with appropriate consent.
- (3) The use of the body of a deceased person for the purpose of anatomical examination shall be lawful if done with appropriate consent.
- (4) Subsections (1) to (3) do not apply to an activity of a kind mentioned there if it is done in relation to —
  - (a) a body to which subsection (5) applies, or
  - (b) an organ or tissue to which subsection (6) applies.
- (5) This subsection applies to a body if —
  - (a) it has been imported into the Island, or

- (b) it is the body of a person who died before the day on which this section comes into force and at least 100 years have elapsed since the date of the person's death.
- (6) This subsection applies to an organ or tissue if —
  - (a) it has been imported into the Island,
  - (b) it has come from a body which has been so imported, or
  - (c) it is an organ or tissue which has come from the body of a person who died before the day on which this section 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 an organ or tissue for use for the purpose of research in connection with disorders, or the functioning, of the human body if —
  - (a) the organ or tissue 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 an organ or tissue for the purpose of research in connection with disorders, or the functioning, of the human body if —
  - (a) the organ or tissue has come from the body of a living person, and
  - (b) the research falls within subsection (9).
- (9) Research falls within this subsection if —
  - (a) it is ethically approved by the Department, and
  - (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 organ or tissue has come can be identified.
- (10) Subsection (1)(f) does not apply to the use of an organ or tissue for the purpose of research where the use of the material would, if undertaken in England, require consent under paragraph 6(1) or 12(1) of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (of Parliament) (use of human cells to create an embryo or a human admixed embryo) or would require such consent but for paragraphs 16 and 20 of that Schedule.
- (11) The following activities are lawful —
  - (a) the storage for use for a purpose specified in Part 2 of Schedule 1 of an organ or tissue which has come from the body of a living person;
  - (b) the use for such a purpose of an organ or tissue which has come from the body of a living person;
  - (c) an activity in relation to which subsection (4), (7), or (8) has effect.
- (12) In the case of an activity in relation to which subsection (8) has effect, subsection (11)(c) is to be read subject to any requirements which would

apply by virtue of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (of Parliament) in relation to the activity if it occurred in England.

- (13) The Department may by order —
- (a) vary or omit any of the purposes specified in Part 1 or 2 of Schedule 1, or
  - (b) add to the purposes specified in Part 1 or 2 of that Schedule.
- (14) Nothing in this section applies to —
- (a) the use of an organ or tissue in connection with a device to which Directive 98/79/EC of the European Parliament and of the Council<sup>7</sup> on in vitro diagnostic medical devices applies, where the use falls within the Directive, or
  - (b) the storage of an organ or tissue for use falling within paragraph (a).
- (15) In this section, the references to a body, an organ or tissue which has been imported into the Island do not include a body, an organ or tissue which has been imported after having been exported from the Island with a view to its subsequently being re-imported into the Island.
- (16) This section is subject to section 16 (exceptions: post-mortems and Coroners).

## **8 Authorisation of activities for scheduled purposes: further provisions**

S2006/4/11 and drafting

- (1) The removal of an organ or tissue from the body of a deceased person for a scheduled purpose may be carried out only by —
- (a) a registered medical practitioner; or
  - (b) a person authorised in accordance with regulations made by the Department.
- (2) Regulations made under subsection (1)(b) may, in particular, provide for a registered medical practitioner to authorise the carrying out of the removal by a person who is not such a practitioner.
- (3) The removal of an organ or tissue from the body of a deceased person may not be —
- (a) carried out for any scheduled purpose unless the person who proposes to carry it out, before doing so, complies with the requirements specified in subsection (4);
  - (b) authorised, by virtue of regulations under subsection (1)(b), unless the registered medical practitioner who proposes to authorise it, before doing so, complies with those requirements.

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<sup>7</sup> (OJ L 331, 7.12.1998, p.1)

- (4) The requirements are that the person (and, where a registered medical practitioner proposes to authorise the carrying out of the removal by virtue of regulations under subsection (1)(b), the practitioner) must be satisfied—
- (a) either—
    - (i) by personal examination of the body, that life is extinct; or
    - (ii) that another registered medical practitioner, by such personal examination, is so satisfied;
  - (b) that, if the consent of the Coroner to the carrying out of the removal is required, the consent has been given; and
  - (c) that the removal is authorised in accordance with section 9, 10, 13 or 14.
- (5) For the purposes of subsection (4)(c), the person or, as the case requires, the registered medical practitioner is entitled to be satisfied that the removal is authorised in accordance with the section in question if, in addition to the requirements of the relevant section, the authorisation satisfies such conditions as may be specified in regulations made by the Department in relation to that section.

## 9 “Appropriate consent”: children

P2004/30/2 (part)

- (1) This section makes provision for the interpretation of “appropriate consent” in section 7 in relation to an activity involving the body, or an organ or tissue from the body, of a person who is a child or has died a child (referred to in this section as “the child concerned”).
- (2) Subject to subsection (3), where the child concerned is alive, “appropriate consent” means his or her consent.
- (3) Where —
- (a) the child concerned is alive,
  - (b) neither a decision of the child to consent to the activity, nor a decision of the child not to consent to it, is in force, and
  - (c) either the child is not competent to deal with the issue of consent in relation to the activity or, though the child is competent to deal with that issue, he or she fails to do so,
- “appropriate consent” means the consent of a person who has parental responsibility for the child.
- (4) Where the child concerned has died and the activity is one to which subsection (5) applies, “appropriate consent” means his or her consent in writing.
- (5) 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.
- (6) Consent in writing for the purposes of subsection (4) is valid only if —
- (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 at the direction of the child concerned, in his or her presence and in the presence of at least one witness who attests the signature.
- (7) Where the child concerned has died and the activity is not one to which subsection (5) applies, “appropriate consent” means —
- (a) if a decision of the child concerned to consent to the activity, or a decision of the child concerned not to consent to it, was in force immediately before the child’s death, his or her consent;
  - (b) if paragraph (a) does not apply —
    - (i) the consent of a person who had parental responsibility for the child concerned immediately before his or her death, or
    - (ii) where no person had parental responsibility for the child immediately before he or she died, the consent of a person, aged at least 18, who stood in a qualifying relationship to the child at that time.

## 10 “Appropriate consent”: adults

P2004/30/3

- (1) This section makes provision for the interpretation of “**appropriate consent**” in section 7 in relation to an activity involving the body, or an organ or tissue from the body, of a person who is an adult or has died an adult (“the person concerned”).
- (2) Where the person concerned is alive, “appropriate consent” means that person’s consent.
- (3) Where the person concerned has died and the activity is one to which subsection (4) applies, “appropriate consent” means the person’s consent in writing.
- (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.
- (5) Consent in writing for the purposes of subsection (3) is valid only if —
  - (a) it is signed by the person concerned in the presence of at least one witness who attests the signature,

- (b) it is signed at the direction of the person concerned, in that person's 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 section 3 of the *Wills Act 1985*.
- (6) Where the person concerned has died and the activity is not one to which subsection (4) applies, "appropriate consent" means —
- (a) if a decision of the person concerned to consent to the activity, or a decision of that person not to consent to it, was in force immediately before he or she died, that person's consent;
  - (b) if —
    - (i) paragraph (a) does not apply, and
    - (ii) the person concerned has appointed a person or persons under section 11 to deal after his or her death with the issue of consent in relation to the activity,  
consent given under the appointment;
  - (c) if neither paragraph (a) nor paragraph (b) applies and the activity is one to which subsection (7) applies, the deemed consent of the person concerned;
  - (d) if neither paragraph (a) nor paragraph (b) applies and the activity is not one to which subsection (7) applies, the consent of a person aged 18 or over who stood in a qualifying relationship to the deceased immediately before he or she died.
- (7) This subsection applies to the following activities done in the Island unless the body is the body of an excepted adult—
- (a) the storage of the body of a deceased person for use for the purpose of transplantation;
  - (b) the removal from the body of a deceased person, for use for the purpose of transplantation, of any organ or tissue of which the body consists or which it contains;
  - (c) the storage for use for the purpose of transplantation of any organ or tissue which has come from a human body;
  - (d) the use for the purpose of transplantation of any organ or tissue which has come from a human body.
- (8) The person concerned is to be deemed, for the purposes of subsection (6)(c), to have consented to the activity unless a person who stood in a qualifying relationship to the person concerned immediately before death provides information that would lead a reasonable person to conclude that the person concerned would not have consented.
- (9) Where the person concerned has appointed a person or persons under section 11 to deal after his or her death with the issue of consent in relation



- to the activity, the appointment is to be disregarded for the purposes of subsection (6) if no one is able to give consent under it.
- (10) If it is not reasonably practicable to communicate with a person appointed under section 11 within the time available if consent in relation to the activity is to be acted on, he or she shall be treated for the purposes of subsection (9) as not able to give consent under the appointment in relation to it.
- (11) In this section “excepted adult” means—
- (a) an adult who has died and who had not been ordinarily resident in the Island 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 effect of subsection (6)(c).
- (12) For the purposes of the definition of “excepted adult” in subsection (11) 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 under subsection (6)(c).

## 11 Nominated representatives

P2004/30/4

- (1) An adult may appoint one or more persons to represent the adult after his or her death in relation to consent for the purposes of section 10.
- (2) An appointment under this section may be general or limited to 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 valid if, but only 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 that person’s 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 3 of the *Wills Act 1985*.
- (6) Where a person appoints two or more persons under this section in relation to the same activity, they shall be regarded as appointed to act jointly and severally unless the appointment provides that they are appointed to act jointly.

- (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.
- (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 —
  - (a) the person is not an adult, or
  - (b) the person is of a description prescribed for the purposes of this provision by regulations made by the Department.

## 12 Prohibition of activities without consent etc.

P2004/30/5

- (1) A person (“P”) commits an offence if, without appropriate consent, P does an activity to which subsection (1), (2) or (3) of section 7 applies, unless P reasonably believes —
  - (a) that P does the activity with appropriate consent, or
  - (b) that what P does is not an activity to which the subsection applies.
- (2) P commits an offence if —
  - (a) P falsely represents to another whom P knows or believes is going to, or may, do an activity to which subsection (1), (2) or (3) of section 7 applies —
    - (i) that there is appropriate consent to the doing of the activity, or
    - (ii) that the activity is not one to which the subsection applies, and
  - (b) P knows that the representation is false or does not believe it to be true.
- (3) For the purposes of this section, “appropriate consent” has the same meaning as it has for the purposes of section 7.

Maximum penalty for an offence under this section—

(on information) — 3 years’ custody;

(summary) — 12 months’ custody or a level 5 fine.

## 13 Activities involving organs or tissue from adults who lack capacity to consent

P2004/30/6

Where —

- (a) an activity of a kind mentioned in section 7(1)(d) or (f) involves an organ or tissue from the body of a person (“D”) who —
  - (i) is an adult, and

- (ii) lacks capacity to consent to the activity, and
- (b) neither a decision of D's to consent to the activity, nor a decision of D's not to consent to it, is in force,

D is to be deemed, for the purposes of this Part, to have consented to the activity if it is done in circumstances of a kind specified by regulations made by the Department.

## 14 Powers to dispense with need for consent

P2004/30/7

- (1) If the Department is satisfied —
  - (a) that an organ or tissue has come from the body of a living person,
  - (b) that it is not reasonably possible to trace the person from whose body the organ or tissue has come (referred to in this section as “the donor”),
  - (c) that it is desirable in the interests of another person (including a future person) that the organ or tissue be used for the purpose of obtaining scientific or medical information about the donor, and
  - (d) that there is no reason to believe —
    - (i) that the donor has died,
    - (ii) that a decision of the donor to refuse to consent to the use of the organ or tissue for that purpose is in force, or
    - (iii) that the donor lacks capacity to consent to the use of the organ or tissue for that purpose,

it may direct that subsection (3) applies to the organ or tissue for the benefit of the other person.

- (2) If the Department is satisfied —
  - (a) that an organ or tissue has come from the body of a living person (the donor),
  - (b) that it is desirable in the interests of another person (including a future person) that the organ or tissue be used for the purpose of obtaining scientific or medical information about the donor,
  - (c) that reasonable efforts have been made to get the donor to decide whether to consent to the use of the organ or tissue for that purpose,
  - (d) that there is no reason to believe —
    - (i) that the donor has died,
    - (ii) that a decision of the donor to refuse to consent to the use of the organ or tissue 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) that the donor has been given notice of the application for the exercise of the power conferred by this subsection,
- it may direct that subsection (3) applies to the organ or tissue for the benefit of the other person.
- (3) Where an organ or tissue is the subject of a direction under subsection (1) or (2), for the purposes of this Part, the donor is to be deemed to have consented to the use of the organ or tissue for the purpose of obtaining scientific or medical information about the donor which may be relevant to the person for whose benefit the direction is given.
- (4) The Department may by regulations enable the High Court, in such circumstances as the regulations may provide, to make an order deeming there to be appropriate consent, for the purposes of this Part, to an activity consisting of —
- (a) the storage of the 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 organ which the body contains or any tissue of which it consists or which it contains,
  - (d) the storage for use for that purpose of any organ or tissue which has come from a human body, or
  - (e) the use for that purpose of any organ or tissue which has come from a human body.

## 15 Restriction of activities in relation to donated material

P2004/30/8

- (1) Subject to subsection (2), a person (“P”) commits an offence if P —
- (a) uses donated material for a purpose which is not a qualifying purpose, or
  - (b) stores donated material for use for a purpose which is not a qualifying purpose.

Maximum penalty —

(on information) 3 years’ custody;

(summary) 12 months’ custody or a level 5 fine.

- (2) Subsection (1) does not apply where P reasonably believes that what P uses, or stores, is not donated material.
- (3) In subsection (1), references to a qualifying purpose are to —
- (a) a purpose specified in Schedule 1,
  - (b) the purpose of medical diagnosis or treatment,

- (c) the purpose of decent clinical disposal, or
  - (d) a purpose specified in regulations made by the Department.
- (4) In this section, references to donated material are to —
- (a) the body of a deceased person, or
  - (b) an organ or tissue which has come from a human body, which is, or has been, the subject of donation.

## 16 Exceptions: post-mortems and Coroners

P2004/30/11 and drafting

- (1) Subject to subsection (2) and (3), nothing in this Part applies to anything done—
- (a) for the purpose of the functions of a Coroner or under the authority of a Coroner; or
  - (b) in the course of or in connection with a post-mortem examination.
- (2) Where a person knows, or has reason to believe, that —
- (a) the body of a deceased person, or
  - (b) an organ or tissue which has come from the body of a deceased person,
- is, or may be, required for purposes of functions of a Coroner, he or she must not act on authority under section 7 in relation to the body, organ or tissue, except with the consent of the Coroner.
- (3) Sections 8 to 11 apply for the purposes of authorising the imposition of conditions under section 65.

## 17 Existing holdings

P2004/30/9

- (1) In its application to the following activities, section 7(1) is to have effect with the omission of the words “if done with appropriate consent” —
- (a) the storage of an existing holding for use for a scheduled purpose;
  - (b) the use of an existing holding for a scheduled purpose.
- (2) Section 12(1) and (2) has effect as if the activities mentioned in subsection (1) were not activities to which section 7(1) applies.
- (3) In this section, “existing holding” means —
- (a) the body of a deceased person, or
  - (b) an organ or tissue which has come from a human body,
- held, immediately before the day on which section 7(1) comes into operation, for use for a purpose specified in Schedule 1.

## PART 3 – REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE AND SUPPLEMENTARY PROVISION

### DIVISION 1: DEPARTMENTAL AND DHSC FUNCTIONS AND REMIT

#### 18 DHSC's remit

P2004/30/14

- (1) The following are the activities within the remit of DHSC under this Act –
- (a) the removal from a human body, for use for a scheduled purpose, of any organ or tissue of which the body consists or which it contains;
  - (b) the use, for a scheduled purpose, of –
    - (i) the body of a deceased person, or
    - (ii) an organ or tissue which has come from a human body;
  - (c) the storage of an anatomical specimen or former anatomical specimen;
  - (d) the storage (in any case not falling within paragraph (c)) of –
    - (i) the body of a deceased person, or
    - (ii) an organ or tissue which has come from a human body, for use for a scheduled purpose;
  - (e) the import or export of –
    - (i) the body of a deceased person, or
    - (ii) an organ or tissue which has come from a human body, for use for a scheduled purpose;
  - (f) the disposal of the body of a deceased person which has been –
    - (i) imported for use,
    - (ii) stored for use, or
    - (iii) used,for a scheduled purpose;
  - (g) the disposal of an organ or tissue which –
    - (i) has been removed from a person's body for the purposes of that person's medical treatment,
    - (ii) has been removed from the body of a deceased person for the purposes of an anatomical, or post-mortem, examination,
    - (iii) has been removed from a human body (otherwise than as mentioned in sub-paragraph (ii)) for use for a scheduled purpose,

- (iv) has come from a human body and been imported for use for a scheduled purpose, or
    - (v) has come from the body of a deceased person which has been imported for use for a scheduled purpose.
  - (h) the procurement, processing, testing, storage, distribution, import or export of tissue or cells, in so far as those activities are activities to which regulation 7(1), (1A) or (2) of the 2007 Regulations applies and are not within the remit of DHSC by virtue of paragraphs (a) to (g);
  - (i) the donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of human organs, in so far as those activities are activities to which regulation 5(1) of the 2012 Regulations applies and are not within the remit of DHSC under this Act by virtue of paragraphs (a) to (h).
- (2) Without limiting subsection (1)(a) and (b), the activities within the remit of DHSC under this Act include, in particular —
- (a) the carrying-out of an anatomical examination, and
  - (b) the making of a post-mortem examination.
- (3) Expressions used in paragraph (h) of subsection (1) and in the 2007 Regulations have the same meaning in that paragraph as in those Regulations; and the reference to activities to which regulation 7(1), (1A) or (2) of those Regulations applies is to be read subject to regulation 2(3) of those Regulations.
- (4) Expressions used in paragraph (i) of subsection (1) and in the 2012 Regulations have the same meaning in that paragraph as in those Regulations.
- (5) An activity is excluded from the remit of DHSC under this Act if —
- (a) it relates to the body of a person who died before the day on which this section comes into force or to an organ or tissue which has come from the body of such a person, and
  - (b) at least 100 years have elapsed since the date of the person's death.
- (6) The Department may by order amend this section for the purpose of adding to the activities within the remit of DHSC under this Act.

## 19 General functions

P2004/30/15 and drafting (sub (2))

- (1) The Department has the following general functions under this Act —
- (a) maintaining a statement of the general principles which it considers should be followed —
    - (i) in the carrying-on of activities under this Act, and
    - (ii) in the carrying-out of functions in relation to such activities;

- (b) providing in relation to activities under this Act such general oversight and guidance as it considers appropriate;
  - (c) superintending, in relation to activities under this Act, compliance with —
    - (i) requirements imposed by or under Part 2 or this Part, and
    - (ii) codes of practice;
  - (d) providing to the public, and to persons carrying on activities under this Act, such information and advice as it considers appropriate about the nature and purpose of such activities.
- (2) Without limiting subsection (1)(d), the Department has a duty to secure appropriate publicity on or about 15<sup>th</sup> March in each year about the desirability of making organs and tissue available for the purposes of transplantation.

## DIVISION 2: LICENSING

### 20 Licence requirement

P2004/30/16 and drafting

- (1) No person shall undertake an activity to which this section applies otherwise than under the authority of a licence granted by the Department for the purposes of this section.
- (2) This section applies to the following activities —
- (a) the carrying-out of an anatomical examination;
  - (b) the making of a post-mortem examination;
  - (c) the removal from the body of a deceased person (otherwise than in the course of an activity mentioned in paragraph (a) or (b)) of an organ or tissue of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;
  - (d) the storage of an anatomical specimen;
  - (e) the storage (in any case not falling within paragraph (d)) of —
    - (i) the body of a deceased person, or
    - (ii) an organ or tissue which has come from a human body, for use for a scheduled purpose;
  - (f) the use, for the purpose of public display, of —
    - (i) the body of a deceased person, or
    - (ii) an organ or tissue which has come from the body of a deceased person.
- (3) This section does not apply to the procurement, testing, processing, storage, distribution, import or export of tissue and cells in so far as those



- activities are activities to which regulation 7(1), (1A) or (2) of the 2007 Regulations applies.
- (4) Expressions used in subsection (3) and in the 2007 Regulations have the same meaning in that subsection as in those Regulations; and the reference to activities to which regulation 7(1), (1A) or (2) of those Regulations applies is to be read subject to regulation 2(3) of those Regulations.
  - (5) The Department may by regulations specify circumstances in which storage of organs or tissue by a person who intends to use them for a scheduled purpose is excepted from subsection (2)(e)(ii).
  - (6) An activity is excluded from subsection (2) if —
    - (a) it relates to the body of a person who died before the day on which this section comes into force or to an organ or tissue which has come from the body of such a person, and
    - (b) at least 100 years have elapsed since the date of the person's death.
  - (7) The Department may by regulations amend this section for the purpose of —
    - (a) adding to the activities to which this section applies,
    - (b) removing an activity from the activities to which this section applies, or
    - (c) altering the description of an activity to which this section applies.
  - (8) The Department must make regulations —
    - (a) about the reconsideration of applications which are refused or which are granted subject to conditions; and
    - (b) about appeals to the High Court on a point of law following a reconsideration.
  - (9) Schedule 2 (which makes provision about licences for the purposes of this section) has effect.
  - (10) In subsection (2) references to storage do not include storage which is incidental to transportation.

## **21 Persons to whom licence applies**

P2004/30/17

The authority conferred by a licence extends to —

- (a) the designated individual,
- (b) any person who is designated as a person to whom the licence applies by a notice given to the Department by the designated individual, and
- (c) any person acting under the direction of —
  - (i) the designated individual, or
  - (ii) a person designated as mentioned in paragraph (b).

## 22 Duty of the designated individual

P2004/30/18

It is the duty of the individual designated in a licence as the person under whose supervision the licensed activity is authorised to be carried on to secure compliance with the conditions of the licence and also to secure —

- (a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity, and
- (b) that suitable practices are used in the course of carrying on that activity.

## 23 Directions following variation or cessation of licence

P2004/30/24

- (1) Directions given by the Department may make provision for the purpose of dealing with a situation arising in consequence of —
  - (a) the variation of a licence, or
  - (b) a licence ceasing to have effect.
- (2) Directions under subsection (1)(a) may impose requirements —
  - (a) on the holder of the licence;
  - (b) on a person who is the designated individual immediately before, or immediately after, the variation;
  - (c) on any other person, if the person consents.
- (3) Directions under subsection (1)(b) may impose requirements —
  - (a) on the person who is the holder of the licence immediately before the licence ceases to have effect;
  - (b) on the person who is the designated individual at that time;
  - (c) on any other person, if the person consents.
- (4) Directions under subsection (1) may, in particular, require anything kept, or information held, in pursuance of the licence to be transferred in accordance with the directions.
- (5) Where a licence has ceased to have effect by reason of the death or dissolution of its holder, anything subsequently done by a person before directions are given under subsection (1) shall, if the licence would have been authority for doing it, be treated as authorised by a licence.

## 24 Breach of licence requirement

P2004/30/25

A person (“P”) who contravenes section 20(1) commits an offence, unless P reasonably believes —

- (a) that what P does is not an activity to which section 20 applies, or

- (b) that P acts under the authority of a licence.
- Maximum penalty —
- (on information) 3 years' custody or a fine or both
- (summary) 12 months' custody or a level 5 fine.

### DIVISION 3: CODES OF PRACTICE

## 25 Preparation of codes of practice

P2004/30/26

- (1) The Department must prepare and issue codes of practice for the purpose of —
- (a) giving practical guidance to persons carrying on activities within its remit under this Act, and
  - (b) laying down the standards expected in relation to the carrying-on of such activities.
- (2) Codes of practice under subsection (1) must deal with the following matters —
- (a) the carrying-out of anatomical examinations;
  - (b) the storage of anatomical specimens;
  - (c) the storage and disposal of former anatomical specimens;
  - (d) the definition of death for the purposes of this Act;
  - (e) communication with the family of the deceased in relation to the making of a post-mortem examination;
  - (f) the making of post-mortem examinations;
  - (g) communication with the family of the deceased in relation to the removal from the body of the deceased, for use for a scheduled purpose, of any organs or tissue of which the body consists or which it contains;
  - (h) the removal from a human body, for use for a scheduled purpose, of any organs or tissue of which the body consists or which it contains;
  - (i) the storage for use for a scheduled purpose, and the use for such a purpose, of —
    - (i) the body of a deceased person, or
    - (ii) any organ or tissue which has come from a human body;
  - (j) the storage for use for a scheduled purpose, and the use for such a purpose, of an existing holding within the meaning of section 17;
  - (k) the import, and the export, of —
    - (i) the body of a deceased person, or
    - (ii) any organ or tissue which has come from a human body,

- for use for a scheduled purpose;
- (l) the disposal of organs or tissue which —
    - (i) has been removed from a human body for use for a scheduled purpose, or
    - (ii) has come from a human body and is an existing holding for the purposes of section 17.
  - (3) In dealing under subsection (1) with the matters mentioned in subsection (2)(h) and (i), the Department must, in particular, deal with consent.
  - (4) The Department must—
    - (a) keep any code of practice under this section under review, and
    - (b) prepare a revised code of practice when appropriate.
  - (5) Before preparing a code of practice under this section, the Department must consult NHSBT and such other persons as it considers appropriate.
  - (6) The Department must publish a code of practice issued under this section in such way as, in its opinion, is likely to bring it to the attention of those interested.
  - (7) A code of practice issued under this section shall come into effect on such day as may be appointed by order.  
Tynwald procedure for an order under this section — laying only.

## 26 Provision about consent

P2004/30/27

- (1) The duty under section 25(3) has effect, in particular, to require the Department to lay down the standards expected in relation to the obtaining of consent where consent falls by virtue of section 9(7)(b)(ii) or 10(6)(d) to be obtained from a person in a qualifying relationship.
- (2) Subject to subsection (3), the standards required to be laid down by subsection (1) shall include provision to the effect set out in subsections (4) to (6).
- (3) The standards required to be laid down by subsection (1) may include provision to different effect in relation to cases which appear to the Department to be exceptional.
- (4) The duty under section 25(3) also has effect, in particular, to require the Department to give practical guidance on the circumstances in which the person concerned is to be deemed to have consented under section 10(8).
- (5) In giving practical guidance by virtue of subsection (4), the Department must, in particular, give guidance about the provision of information of the type described in section 10(8) by a person who stood in a qualifying relationship to the person concerned immediately before death.
- (6) The Department may by order amend subsection (4).

**27 Effect of codes**

P2004/30/28

- (1) A failure on the part of any person to observe any provision of a code of practice under section 25 shall not of itself render the person liable to any proceedings.
- (2) The Department may, in carrying out its functions with respect to licences, take into account any relevant observance of, or failure to observe, a code of practice under section 25 so far as dealing with a matter mentioned in any of paragraphs (a) to (c) and (e) to (j) of subsection (2) of that section.

**28 Laying of codes**

Section 34 of the *Legislation Act 2015* applies to a code of practice under this Division as it applies to a statutory document.

## DIVISION 4: ANATOMY

**29 Possession of anatomical specimens away from licensed premises**

P2004/30/30

- (1) A person commits an offence if —
  - (a) he or she has possession of an anatomical specimen, and
  - (b) the specimen is not on premises in respect of which an anatomy licence is in force.

This is subject to subsections (2) to (6).

Maximum penalty —

(on information) — 3 years' custody;

(summary) — 12 months' custody or fine not exceeding level 5.

- (2) Subsection (1) does not apply where —
  - (a) the specimen has come from premises in respect of which a storage licence is in force, and
  - (b) the person —
    - (i) is authorised in writing by the designated individual to have possession of the specimen, and
    - (ii) has possession of the specimen only for a purpose for which he or she is so authorised to have possession of it.
- (3) Subsection (1) does not apply where —
  - (a) the specimen is the body of a deceased person which is to be used for the purpose of anatomical examination,
  - (b) the person who has possession of the body has come into lawful possession of it immediately after the deceased's death, and

- (c) he or she retains possession of the body prior to its removal to premises in respect of which an anatomy licence is in force.
- (4) Subsection (1) does not apply where the person has possession of the specimen only for the purpose of transporting it to premises —
  - (a) in respect of which an anatomy licence is in force, or
  - (b) where the specimen is to be used for the purpose of education, training or research.
- (5) Subsection (1) does not apply where the person has possession of the specimen for purposes of functions of, or under the authority of, a Coroner.
- (6) Subsection (1) does not apply where the person reasonably believes —
  - (a) that what he or she has possession of is not an anatomical specimen,
  - (b) that the specimen is on premises in respect of which an anatomy licence is in force, or
  - (c) that any of subsections (2) to (5) applies.
- (7) In this section —

“anatomy licence” means a licence issued by the Department under section 20 authorising —

  - (a) the carrying-out of an anatomical examination, or
  - (b) the storage of anatomical specimens;

“storage licence” means a licence authorising the storage of anatomical specimens.

### **30 Possession of former anatomical specimens away from licensed premises**

P2004/30/31

- (1) A person commits an offence if —
  - (a) he or she has possession of a former anatomical specimen, and
  - (b) the specimen is not on premises in respect of which a storage licence is in force.

This is subject to subsections (2) to (5).

Maximum penalty —

(on information)	3 years’ custody; or
(summary)	12 months’ custody or level 5 fine.
- (2) Subsection (1) does not apply where —
  - (a) the specimen has come from premises in respect of which a storage licence is in force, and
  - (b) the person —

- (i) is authorised in writing by the designated individual to have possession of the specimen, and
  - (ii) has possession of the specimen only for a purpose for which he or she is so authorised to have possession of it.
- (3) Subsection (1) does not apply where the person has possession of the specimen only for the purpose of transporting it to premises —
- (a) in respect of which a storage licence is in force, or
  - (b) where the specimen is to be used for the purpose of education, training or research.
- (4) Subsection (1) does not apply where the person has possession of the specimen —
- (a) only for the purpose of its decent disposal, or
  - (b) for purposes of functions of, or under the authority of, a Coroner.
- (5) Subsection (1) does not apply where the person reasonably believes —
- (a) that what he or she has possession of is not a former anatomical specimen,
  - (b) that the specimen is on premises in respect of which a storage licence is in force, or
  - (c) that any of subsections (2) to (4) applies.
- (6) In this section, “storage licence” means a licence authorising the storage, for use for a scheduled purpose, of a human body or an organ or tissue which has come from a human body.

#### DIVISION 5: TRAFFICKING

### **31 Prohibition of commercial dealings in human material for transplantation**

P2004/30/32

- (1) A person (“P”) commits an offence if P—
- (a) gives or receives a reward for the supply of, or for an offer to supply, any controlled material;
  - (b) seeks to find a person willing to supply any controlled material for reward;
  - (c) offers to supply any controlled material for reward;
  - (d) initiates or negotiates any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any controlled material.

Maximum penalty—

(on information) 3 years’ custody;

(summary) 12 months’ custody or a level 5 fine.

- (2) Without limiting subsection (1)(b) and (c), P commits an offence if P causes to be published or distributed, or knowingly publishes or distributes, an advertisement –
- (a) inviting persons to supply, or offering to supply, any controlled material for reward, or
  - (b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned in subsection (1)(d).

Maximum penalty (summary) 12 months' custody or a level 5 fine.

- (3) Where P engages in an activity to which subsection (1) or (2) applies, P does not commit an offence under that subsection if P is designated by the Department as a person who may lawfully engage in the activity.
- (4) The Department may not designate a person under subsection (3) if doing so could result in the United Kingdom being in breach of –
- (a) Article 12 of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004<sup>8</sup> on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, or
  - (b) Article 13 of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010<sup>9</sup> on standards of quality and safety of human organs intended for transplantation.
- (5) For the purposes of subsections (1) and (2), payment in money or money's worth to the holder of a licence is not to be treated as a reward where –
- (a) it is in consideration for transporting, removing, preparing, preserving or storing controlled material, and
  - (b) its receipt by the holder of the licence is not expressly prohibited by the terms of the licence.
- (6) References in subsections (1) and (2) to reward, in relation to the supply of any controlled material, do not include payment in money or money's worth for defraying or reimbursing –
- (a) any expenses incurred in, or in connection with, transporting, removing, preparing, preserving or storing the material,
  - (b) any liability incurred in respect of –
    - (i) expenses incurred by a third party in, or in connection with, any of the activities mentioned in paragraph (a), or
    - (ii) a payment in relation to which subsection (5) has effect, or

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<sup>8</sup> OJ L 102, 7.4.2004, pp 48-58.

<sup>9</sup> OJ L 207 6.8.2010, p. 14.



- (c) any expenses or loss of earnings incurred by the person from whose body the material comes (“D”) so far as reasonably and directly attributable to D’s supplying the material from D’s body.
- (7) For the purposes of this section, controlled material is any material which —
  - (a) consists of or includes human cells,
  - (b) is, or is intended to be removed, from a human body,
  - (c) is intended to be used for the purpose of transplantation, and
  - (d) is not of a kind excepted under subsection (8).
- (8) The following kinds of material are excepted —
  - (a) gametes,
  - (b) embryos, and
  - (c) material which is the subject of intellectual property rights because of an application of human skill.
- (9) Where the body of a deceased person is intended to be used to provide material which —
  - (a) consists of or includes human cells, and
  - (b) is not of a kind excepted under subsection (8),for use for the purpose of transplantation, the body is to be treated as controlled material for the purposes of this section.
- (10) In this section —
  - “advertisement” includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons;
  - “reward” means any description of financial or other material advantage.

#### DIVISION 6: TRANSPLANTS

### **32 Restriction on transplants involving a live donor**

P2004/30/33

- (1) Subject to subsections (3) and (5), a person (“P”) commits an offence if —
  - (a) P removes any transplantable material from the body of a living person intending that the material be used for the purpose of transplantation, and
  - (b) when P removes the material, P knows, or might reasonably be expected to know, that the person from whose body P removes the material is alive.
- (2) Subject to subsections (3) and (5), P commits an offence if —
  - (a) P uses for the purpose of transplantation any transplantable material which has come from the body of a living person, and

- (b) when P does so, P knows, or might reasonably be expected to know, that the transplantable material has come from the body of a living person.
- (3) The Department may by regulations provide that subsection (1) or (2) shall not apply in a case where —
  - (a) it is satisfied —
    - (i) that no reward has been or is to be given in contravention of section 31, and
    - (ii) that such other conditions as are specified in the regulations are satisfied, and
  - (b) such other requirements as are specified in the regulations are complied with.
- (4) Regulations under subsection (3) must include provision for decisions of the Department in relation to matters which fall to be decided by it under the regulations to be subject, in such circumstances as the regulations may provide, to reconsideration in accordance with such procedure as the regulations may provide.
- (5) Where under subsection (3) an exception from subsection (1) or (2) is in force, P does not commit an offence under that subsection if P reasonably believes that the exception applies.
- (6) In this section —

“reward” has the same meaning as in section 31;

“transplantable material” means material of a description specified by regulations made by the Department.

Maximum penalty (summary) 12 months’ custody or a level 5 fine.

### **33 Information about transplant operations**

P2004/30/34

- (1) The Department may make regulations about transplants that have been, or are, proposed to be carried out using transplantable material removed from a human body.
- (2) Regulations under this section may (among other things) require such persons as may be specified to supply to such authority as may be specified such information as may be specified.  
Here “specified” means specified in the regulations.
- (3) Any such authority must keep a record of information supplied to it under regulations under this section.
- (4) A person commits an offence if —
  - (a) he or she fails without reasonable excuse to comply with regulations under this section, or

- (b) in purported compliance with such regulations, he or she knowingly or recklessly supplies information which is false or misleading in a material respect.  
Maximum penalty (summary)—
  - (a) for an offence under paragraph (a), a fine not exceeding level 3;
  - (b) for an offence under paragraph (b), a fine not exceeding level 5.
- (5) In this section, “transplantable material” has the same meaning as in section 32.

#### DIVISION 7: GENERAL

### **34 Arrangements about the provision of services**

P2004/30/35

- (1) The Department and DHSC may each enter into arrangements with another Department, a public authority (within the meaning of section 6 of the Freedom of Information Act 2015), or a person including the holder of a public office (“the other authority”) whether inside the Island or elsewhere for —
  - (a) any functions of the Department or DHSC to be carried out by, or by members of staff of, the other authority, or
  - (b) the provision by the other authority of administrative, professional or technical services to the Department or DHSC.
- (2) Arrangements under subsection (1)(a) do not affect responsibility for the carrying-out of the functions of the Department or DHSC (as the case requires).
- (3) Subsection (1)(a) does not apply to functions of making statutory documents.

### **35 Annual report**

P2004/30/36

- (1) The Department must produce an annual report on the operation of this Act.
- (2) The first such report is to be produced within one month of the first anniversary of the date on which this section comes into operation.
- (3) Each succeeding report is to be produced within one month of the anniversary of the date on which the preceding report was produced.
- (4) A report under this section shall deal with the activities of the Department and the DHSC under this Act in the period to which the report relates.
- (5) A report under this section must be laid before Tynwald as soon as reasonably practicable after its production.

- (6) The Department must send a copy of each report under this section to the Secretary of State responsible for health in England, as soon as practicable after the end of the period to which the report relates.

## 36 Directions

P2004/33/37

- (1) The Department may give directions for any purpose for which directions may be given under this Act.
- (2) Any power to give directions includes power to vary or revoke directions given in previous exercise of the power.
- (3) Any power to give directions is exercisable by instrument in writing.
- (4) Directions to a particular person shall be given by serving notice of the directions on the person.
- (5) Directions in respect of any licence (including one which has ceased to have effect) may be given –
  - (a) by serving notice of the directions on the person who is (or was immediately before the cessation) the designated individual or holder of the licence, or
  - (b) if it appears to the Department that it is not practicable to give notice in that way, by publishing the directions in such way as, in its opinion, is likely to bring them to the attention of the persons to whom they are applicable.
- (6) Directions under this Part which appear to the Department to be general directions may be given by publishing them as mentioned in subsection (5)(b).
- (7) Directions to which subsection (6) applies are public documents for the purposes of the *Interpretation Act 2015* and the *Legislation Act 2015*, but not statutory documents for the purposes of those Acts.
- (8) This section does not apply to directions under Schedule 2.

## 37 Duties in relation to carrying out functions

P204/30/38 (adapted)

- (1) The Department and DHSC must carry out their functions under this Act effectively, efficiently and economically.
- (2) In carrying out their functions under this Act, the Department and DHSC must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

## DIVISION 8: EXCEPTIONS

**38 Criminal justice purposes**

P2004/30/39

- (1) Subject to subsection (2), nothing in section 18(1) or 20(2) applies to anything done for purposes related to —
  - (a) the prevention or detection of crime, or
  - (b) the conduct of a prosecution.
- (2) Subsection (1) does not except from section 18(1) or 20(2) the carrying-out of a post-mortem examination for purposes of functions of a coroner.
- (3) The reference in subsection (2) to the carrying-out of a post-mortem examination does not include the removal of an organ or tissue from the body of a deceased person, or from a part of the body of a deceased person, at the first place where the body or part is situated to be attended by a constable.
- (4) For the purposes of subsection (1)(a), detecting crime shall be taken to include —
  - (a) establishing by whom, for what purpose, by what means and generally in what circumstances any crime was committed, and
  - (b) the apprehension of the person by whom any crime was committed;and the reference in subsection (1)(a) to the detection of crime includes any detection outside the Island of any crime or suspected crime.
- (5) In subsection (1)(b), the reference to a prosecution includes a prosecution brought in respect of any crime in a country or territory outside the Island.
- (6) In this section, references to crime include a reference to any conduct which —
  - (a) constitutes one or more criminal offences (whether under the law of the Island or of a country or territory outside the Island),
  - (b) is, or corresponds to, any conduct which, if it all took place in the Island, would constitute one or more criminal offences, or
  - (c) constitutes one or more service offences within the meaning of the Armed Forces Act 2006 (of Parliament)<sup>10</sup> as that Act applies in the Island.

**39 Religious relics**

P2004/30/40

- (1) This section applies —
  - (a) to the use of —

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<sup>10</sup> <sup>10</sup> 2006 c. 52.

- (i) the body of a deceased person, or
  - (ii) an organ or tissue which has come from a human body, for the purpose of public display at a place of public religious worship or at a place associated with such a place, and
- (b) to the storage of —
  - (i) the body of a deceased person, or
  - (ii) an organ or tissue which has come from a human body, for use for the purpose mentioned in paragraph (a).
- (2) An activity to which this section applies is excluded from sections 18(1) and 20(2) if there is a connection between —
  - (a) the body or material to which the activity relates, and
  - (b) the religious worship which takes place at the place of public religious worship concerned.
- (3) For the purposes of this section, a place is associated with a place of public religious worship if it is used for purposes associated with the religious worship which takes place there.

## PART 4 – POST-MORTEM EXAMINATIONS

### 40 Meaning of post-mortem examination for purposes of Act

S2006/4/23

In this Act, “**post-mortem examination**” means examination of the body of a deceased person involving its dissection and the removal of organs, tissue sample, blood (or any material derived from blood) or other body fluid which is carried out for any or all of the following purposes —

- (a) providing information about or confirming the cause of death;
- (b) investigating the effect and efficacy of any medical or surgical intervention carried out on the person;
- (c) obtaining information which may be relevant to the health of any other person (including a future person);
- (d) audit, education, training or research.

### 41 Sections 44 to 54 not to apply to the Coroner

S2006/4/24 and drafting.

Section 44 to 54 do not apply to anything done for the purposes of the functions or under the authority of the Coroner.

**42 Sections 44 to 52 and 54 not to apply to bodies of persons dead for at least 100 years**

S2006/4/25

Sections 44 to 52 and 54 do not apply as respects a post-mortem examination of a body of a deceased person if it is the body of a person who died before the day on which section 44 comes into force and at least 100 years have elapsed since the date of the person's death.

**43 Consent of Coroner to post-mortem examination**

S2006/4/26

- (1) Where a person knows, or has reason to believe, that an examination of the body of a deceased person is, or may be, required for the purposes of the functions of the Coroner, the person may not, except with the consent of the Coroner, carry out a post-mortem examination of the body.
- (2) A person who acts in breach of subsection (1) commits an offence.  
Maximum penalty (summary) 12 months' custody or a level 5 fine.
- (3) For the purposes of subsection (1), consent by the Coroner may be given orally and if so given is to be confirmed in writing as soon as is reasonably practicable.

**44 Requirements for carrying out post-mortem examination**

S2006/4/27

A post-mortem examination may be carried out only if—

- (a) it is authorised in accordance with section 46, 47, 48, 49 or 50 (as the case requires); and
- (b) the requirements of section 52 are satisfied.

**45 Removal during examination and retention of organs and other parts of a body**

S2006/4/28

- (1) Subject to section 43 and subsection (2), any part of the body of a deceased person mentioned in subsection (5) may, by virtue of the authorisation for the post-mortem examination of the body, be—
  - (a) removed from the body during the post-mortem examination for the purposes of the examination;
  - (b) retained and used thereafter for any of those purposes.
- (2) An organ may be—
  - (a) removed, for the purposes of audit, education, training or research, from the body of a deceased person during a post-mortem examination of the body only if the removal for the purpose in question, or

- (b) retained and used thereafter for any of those purposes only if the retention for the purpose in question,  
is authorised in accordance with section 46, 47, 48, 49 or 50 (as the case requires).
- (3) Any part of the body of a deceased person (other than an organ) which is removed from the body during the post-mortem examination by virtue of the authorisation referred to in subsection (1) forms part of the medical records of the deceased person.
- (4) Where an organ is removed from the body of a deceased person during the post-mortem examination of the body (whether by virtue of the authorisation referred to in subsection (1) or (2)), samples—
  - (a) may, by virtue of the authorisation, be taken from the organ; and
  - (b) if taken, form part of the medical records of the deceased person.
- (5) The parts of the body referred to in subsection (1) are—
  - (a) an organ;
  - (b) tissue sample;
  - (c) blood, or any material derived from blood;
  - (d) other body fluid.
- (6) A part of the body of a deceased person which is not mentioned in subsection (5) may not be removed from the body during a post-mortem examination of the body.

#### **46 Authorisation of post-mortem examination etc.: adult**

S2006/4/29

- (1) An adult may authorise—
  - (a) a post-mortem examination of the adult's body after the adult's death;
  - (b) the removal from the body during the post-mortem examination of an organ for one or more of the purposes referred to in section 45(2)(a);
  - (c) the retention and use of an organ after the post-mortem examination for one or more of such purposes.
- (2) Authorisation by virtue of subsection (1) must be either—
  - (a) in writing and signed by the adult; or
  - (b) expressed orally in the presence of 2 witnesses.
- (3) Authorisation by virtue of subsection (1) which is—
  - (a) in writing and signed may be withdrawn in writing signed by the adult;



- (b) expressed orally in the presence of 2 witnesses may be withdrawn—
  - (i) in writing signed by the adult; or
  - (ii) orally by the adult in the presence of 2 witnesses.
- (4) If the adult is blind or unable to write, an authorisation by virtue of subsection (2)(a) and the withdrawal of authorisation by virtue of subsection (3)(a) may be signed by another adult (a “signatory”) on the adult’s behalf and if it is so signed it must be witnessed by one witness.
- (5) An authorisation and the withdrawal of authorisation-which is signed by a signatory on behalf of an adult by virtue of subsection (4) must contain a statement signed by both the signatory and the witness in the presence of the adult and of each other that the adult, in the presence of them both, expressed the intention to make the authorisation, or as the case may be, withdraw the authorisation and requested the signatory to sign the authorisation or as the case may be, the withdrawal on behalf of the adult.

#### **47 Authorisation of post-mortem examination etc. by adult’s nominee or person in qualifying relationship**

S2006/4/30

- (1) An adult may nominate one or more persons to represent the adult after the adult’s death as respects authorising in relation to the deceased adult one or more of the matters referred to in section 46(1).
- (2) A person who stood in a qualifying relationship to the deceased adult immediately before his or her death may authorise one or more of the matters referred to in that section in relation to the deceased adult if there is in force immediately before the adult’s death no authorisation by the adult by virtue of section 46 of any of the matters referred to in that section and no nomination by the adult in accordance with subsection (1).
- (3) Where an adult has nominated a person by virtue of subsection (1), the nomination is to be disregarded if—
  - (a) no one is able to give authorisation under it; or
  - (b) it is not reasonably practicable to communicate with the person in the time available,and where the nomination falls under this subsection to be disregarded, subsection (2) applies as if there were in force immediately before the adult’s death no such nomination by the adult.
- (4) Authorisation by a person nominated by virtue of subsection (1) must be in writing signed by the person and witnessed by one witness (who must not be so nominated).
- (5) Authorisation by virtue of subsection (2) must be in writing signed by the person who stood in a qualifying relationship with the deceased immediately before his or her death and witnessed by one witness.

- (6) Authorisation—
- (a) by a person nominated by virtue of subsection (1), or
  - (b) by virtue of subsection (2),
- must state that the person giving the authorisation has no actual knowledge that the adult was unwilling for a post-mortem examination to be carried out and, where the authorisation is of an activity referred to in section 46(1)(b) or (c), for the activity in question to be carried out (for the purpose in question).
- (7) Authorisation by a person nominated by virtue of subsection (1) may be withdrawn in writing signed by the person and witnessed by one witness (who must not be so nominated).
- (8) Authorisation by virtue of subsection (2) may be withdrawn in writing signed by the person who gave it and witnessed by one witness.

#### **48 Authorisation of post-mortem examination etc.: child 12 years of age or over**

S2006/4/31

- (1) A child who is 12 years of age or over may authorise—
- (a) a post-mortem examination of the deceased child's body after the child's death;
  - (b) the removal from the body during the post-mortem examination of an organ for one or more of the purposes referred to in section 45(2)(a);
  - (c) the retention and use of an organ after the post-mortem examination for one or more of such purposes.
- (2) Authorisation by virtue of subsection (1)—
- (a) must be in writing—
    - (i) signed by the child and witnessed by 2 witnesses; or
    - (ii) subject to subsections (3) and (4), if the child is blind or unable to write signed by an adult (a “signatory”) on the child's behalf and witnessed by one witness;
  - (b) may be withdrawn in writing—
    - (i) signed by the child; or
    - (ii) subject to subsections (3) and (4), if the child is blind or unable to write signed by an adult (a “signatory”) on the child's behalf and witnessed by one witness.
- (3) Authorisation by virtue of subsection (1), or withdrawal of such authorisation, which is signed by a signatory on behalf of the child by virtue of subsection (2)(a)(ii) or (b)(ii) must contain a statement signed by both the signatory and the witness in the presence of the child and of each other that the child, in the presence of them both, expressed the intention

to give or withdraw the authorisation and requested the signatory to sign the authorisation or, as the case requires, the withdrawal on behalf of the child.

- (4) Authorisation by virtue of subsection (1) which is signed by a signatory on behalf of a child by virtue of subsection (2)(a)(ii) must contain or be accompanied by certification in writing signed by the signatory that, in the opinion of the signatory, the child understands the effect of the authorisation and is not acting under undue influence in giving it.
- (5) Nothing in subsection (2)(a)(ii) or (b)(ii) prevents a child who is blind from signing an authorisation by virtue of subsection (1) in accordance with subsection (2)(a)(i) or a withdrawal of authorisation in accordance with subsection (2)(b)(i).
- (6) Each witness to authorisation by a child by virtue of subsection (1) (whether it is signed by the child or by a signatory on behalf of the child), must at the time of witnessing certify (in writing signed by the witness) that, in the opinion of the witness, the child understands the effect of the authorisation and is not acting under undue influence in giving it.

#### **49 Authorisation of post-mortem examination etc. as respects child 12 years of age or over by nominee or person with parental responsibility**

S2006/4/32

- (1) A child who is 12 years of age or over may nominate one or more persons to represent the child after the child's death as respects authorising in relation to the deceased child one or more of the matters referred to in section 48(1).
- (2) A person who immediately before the death of a child who died 12 years of age or over had parental responsibility in relation to the child (but who is not DHSC) may authorise one or more of the matters referred to in that section in relation to the deceased child if there is in force immediately before the death no authorisation by the child by virtue of that section of any of the matters referred to in it and no nomination by the child in accordance with subsection (1).
- (3) Where a child who died 12 years of age or over has nominated a person by virtue of subsection (1), the nomination is to be disregarded if—
  - (a) no one is able to give authorisation under it; or
  - (b) it is not reasonably practicable to communicate with the person in the time available,

and where the nomination falls under this subsection to be disregarded, subsection (2) applies as if there were in force immediately before the child's death no such nomination by the child.

- (4) Authorisation by a person nominated by virtue of subsection (1) must be in writing signed by the person and witnessed by 2 witnesses (who must not be so nominated).
- (5) Authorisation by virtue of subsection (2) must be in writing signed by the person who gives the authorisation in accordance with that subsection and witnessed by 2 witnesses.
- (6) Authorisation—
  - (a) by a person nominated by virtue of subsection (1), or
  - (b) by virtue of subsection (2),must state that the person giving the authorisation has no actual knowledge that the child was unwilling for a post-mortem examination to be carried out and, where the authorisation is of an activity referred to in section 48(1)(b) or (c), for the activity in question to be carried out (for the purpose in question).
- (7) Authorisation by a person nominated in accordance with subsection (1) may be withdrawn in writing signed by the person and witnessed by 2 witnesses (who must not be so nominated).
- (8) Authorisation by virtue of subsection (2) may be withdrawn in writing signed by the person who gave the authorisation in accordance with that subsection and witnessed by 2 witnesses.

## **50 Authorisation of post-mortem examination etc. as respects child under 12 years of age**

S2006/4/33

- (1) A person who immediately before the death of a child who died under 12 years of age had parental responsibility in relation to the child (other than DHSC) may authorise one or more of the matters referred to in section 48(1) as respects the deceased child.
- (2) Authorisation by virtue of subsection (1)—
  - (a) must be in writing signed by the person who gives the authorisation in accordance with that subsection and witnessed by 2 witnesses;
  - (b) may be withdrawn in writing so signed and witnessed by one witness.
- (3) If the person referred to in subsection (1) is blind or unable to write, an authorisation or its withdrawal may be signed by an adult (a “signatory”) on that person’s behalf and if it is so signed it must be witnessed by 2 witnesses.

**51 Nomination of person under section 47(1) or 49(1): additional provision**

S2006/4/34

- (1) Nomination by virtue of—
  - (a) section 47(1)—
    - (i) must be in writing signed by the adult;
    - (ii) may be withdrawn in writing signed by the adult, in the presence of one witness (who is not so nominated);
  - (b) section 49(1)—
    - (i) must be in writing signed by the child;
    - (ii) may be withdrawn in writing signed by the child, in the presence of one witness (who is not so nominated).
- (2) A witness to nomination by an adult by virtue of section 47(1) or by a child by virtue of section 49(1) must at the time of witnessing certify (in writing signed by the witness) that, in the opinion of the witness, the adult or, as the case requires, the child understands the effect of the nomination and is not acting under undue influence in giving it.
- (3) A person nominated by virtue of 47(1) or section 49(1)—
  - (a) may not act under the nomination if not an adult;
  - (b) may renounce the nomination.
- (4) Where more than one person is so nominated, authorisation by virtue of the nomination may be given by any one of them or by all of them acting jointly.
- (5) If the person referred to in subsection (1)(a) or the child referred to in subsection (1)(b) is blind or unable to write, an authorisation or its withdrawal may be signed by an adult (a “signatory”) on the adult’s, or as the case may be, the child’s behalf and if it is so signed it must be witnessed by one witness.

**52 Post-mortem examination and removal and retention of organs: further requirements**

S2006/4/35

- (1) An activity mentioned in subsection (2) may not be carried out unless the person who proposes to carry it out is satisfied before doing so—
  - (a) that the activity is authorised in accordance with section 46, 47, 48, 49 or 50, as the case requires; and
  - (b) as respects the carrying out of a post-mortem examination that, if the consent of the Coroner to carrying it out is required by section 43(1), the consent has been given.
- (2) The activities are—
  - (a) a post-mortem examination;

- (b) removal of an organ during the examination for a purpose referred to in section 45(2)(a);
  - (c) retention and use of an organ for such a purpose after removal.
- (3) For the purposes of subsection (1)(a), the person is entitled to be satisfied that the activity is authorised in accordance with the section in question if—
- (a) the person has no reason to believe either that the authorisation was not so given or that it was subsequently withdrawn;
  - (b) in the case of authorisation by virtue of section 46(1) which is in writing, it appears—
    - (i) to relate to the deceased adult;
    - (ii) to authorise the activity in question (and, where the activity in question is that referred to in subsection (2)(b) or (c), to authorise the purpose in question);
    - (iii) to be by, and signed by, the adult (A) or signed by another adult on A's behalf where A was blind or unable to write at the time of giving the authorisation and if it is so signed by another adult it must be witnessed by one witness;
  - (c) in the case of authorisation by virtue of section 46(1) which is expressed orally, there is what the person considers to be an appropriate record of the authorisation and the authorisation appears on its face—
    - (i) to relate to the deceased adult;
    - (ii) to authorise the activity in question (and, where the activity in question is that referred to in subsection (2)(b) or (c), to authorise the purpose in question);
    - (iii) to have been expressed orally by the adult in the presence of 2 witnesses, each of whom was an adult when witnessing and was present when the other witnessed the authorisation;
  - (d) in the case of authorisation by a nominee by virtue of section 47(1) or authorisation by virtue of section 47(2) it is in writing and appears—
    - (i) to relate to the deceased adult;
    - (ii) to authorise the activity in question (and, where the activity in question is that referred to in subsection (2)(b) or (c), to authorise the purpose in question);
    - (iii) to be by a nominee (N) of the deceased adult and signed by N or where N was blind or unable to write at the time of giving the authorisation, signed by another adult on N's behalf or, as the case requires, to be by a person (P) who stood in a qualifying relationship to the deceased adult and

- signed by P or where P was blind or unable to write at the time of giving the authorisation, signed by another adult on P's behalf;
- (iv) to state that the person who gave the authorisation had when authorising no actual knowledge that the adult was unwilling for a post-mortem examination to be carried out and, where the authorisation is of an activity referred to in subsection (2)(b) or (c), for the activity in question to be carried out (for the purpose in question);
  - (v) to be witnessed, and signed, by one witness who was an adult when witnessing;
  - (vi) if by a nominee by virtue of section 47(1), to state that the nominee was an adult when giving the authorisation;
  - (vii) to be in the form prescribed for such authorisation;
- (e) in the case of authorisation by virtue of section 48(1) which is not signed by a person on behalf of the child, it is in writing and appears—
- (i) to relate to the deceased child;
  - (ii) to authorise the activity in question (and, where the activity in question is that referred to in subsection (2)(b) or (c), to authorise the purpose in question);
  - (iii) to be given by, and signed by, the child while 12 years of age or over;
  - (iv) to be witnessed, and signed, by 2 witnesses each of whom was an adult when witnessing and was present when the other witnessed the authorisation;
  - (v) to contain or be accompanied by certification in writing by, and signed by, each witness that in the opinion of the witness the child understood the effect of the authorisation and was not acting under undue influence in giving it;
- (f) in the case of authorisation by virtue of section 48(1) which is signed by a person on behalf of the child, it is in writing and appears—
- (i) to relate to the deceased child;
  - (ii) to authorise the activity in question (and, where the activity in question is that referred to in subsection (2)(b) or (c), to authorise the purpose in question);
  - (iii) to be on behalf of the child while 12 years of age or over;
  - (iv) to be signed by an adult on behalf of the child because the child was blind or unable to write at the time of giving the authorisation;

- (v) to be witnessed by one witness who was an adult when witnessing and was present when the other adult signing the authorisation signed it;
  - (vi) to contain a statement signed by both the signatory and the witness in the presence of the child and of each other that the child, in the presence of them both, expressed the intention to give the authorisation and requested the signatory to sign it on the child's behalf;
  - (vii) to contain or be accompanied by certification in writing signed by the person signing the authorisation on behalf of the child that, in the opinion of the person, the child understood the effect of the authorisation and was not acting under undue influence in giving it and by certification in writing signed by the witness that, in the opinion of the witness, the child so understood and was not so acting;
- (g) in the case of authorisation by a nominee by virtue of section 49(1) or authorisation by virtue of section 49(2), it is in writing and appears—
- (i) to relate to the deceased child (who died 12 years of age or over);
  - (ii) to authorise the activity in question (and, where the activity in question is that referred to in subsection (2)(b) or (c), to authorise the purpose in question);
  - (iii) to be by a nominee (N) of the deceased child and signed by N or where N was blind or unable to write at the time of giving the authorisation, signed by another adult on the N's behalf or, as the case requires, to be by a person (P) who immediately before the child's death had parental responsibility in relation to the child (other than DHSC) and signed by P or where P was blind or unable to write at the time of giving the authorisation, signed by another adult on P's behalf;
  - (iv) to state that the person who gave the authorisation had no actual knowledge that the child was unwilling for a post-mortem examination to be carried out and, where the authorisation relates to an activity referred to in subsection (2)(b) or (c), for the activity in question to be carried out (for the purpose in question);
  - (v) to be witnessed, and signed, by 2 witnesses each of whom was an adult when witnessing and was present when the other witnessed the authorisation;
  - (vi) if by a nominee by virtue of section 49(1), to state that the nominee was an adult when giving the authorisation;



- (vii) to be in the form prescribed for such authorisation;
- (h) in the case of authorisation by virtue of section 50(1), it is in writing and appears—
  - (i) to relate to the deceased child (who died under 12 years of age);
  - (ii) to authorise the activity in question (and, where the activity in question is that referred to in subsection (2)(b) or (c), to authorise the purpose in question);
  - (iii) to be by a person who, immediately before the child's death, had parental responsibility in relation to the child (other than DHSC) and to be signed by the person or where the person was blind or unable to write at the time of giving the authorisation signed by another adult on the person's behalf;
  - (iv) to be witnessed, and signed, by 2 witnesses each of whom was an adult when witnessing and was present when the other witnessed the authorisation;
  - (v) to be in the form prescribed for such authorisation.

### **53 Organ or tissue sample removed before day on which section 44 comes into operation**

S2006/4/36

An organ or tissue sample—

- (a) removed from the body of a deceased person during an examination having the characteristics of a post-mortem examination carried out before the day on which section 44 comes into operation; and
- (b) held immediately before that day for use for any purpose referred to in paragraphs (a) to (d) of section 40,

may be retained and used for any such purpose.

### **54 Offences: post-mortem examinations**

S2006/4/37

- (1) A person commits an offence if—
  - (a) the person carries out any of the following activities—
    - (i) a post-mortem examination;
    - (ii) the removal, for a purpose referred to in section 45(2)(a), of an organ during a post-mortem examination;
    - (iii) the retention, for such a purpose, of an organ removed during a post-mortem examination; and

- (b) the activity is not authorised in accordance with section 46, 47, 48, 49 or 50 as the case requires.
- (2) Where a person is charged with an offence under subsection (1) it is a defence for the person to show that, at the time of carrying out the activity, the person reasonably believed that the activity was authorised in accordance with section 46, 47, 48, 49 or 50 as the case requires.

Maximum penalty —

- (a) (on information) – 3 years’ custody or a fine;
- (b) (summary) – 12 months’ custody or a level 5 fine.

## **55 Tissue sample becoming part of medical records of deceased person**

S2006/4/38 and drafting

- (1) This section applies to a tissue sample removed from the body of a deceased person (or from an organ which was removed from the body) during an examination of the body, carried out on or after the day on which this section comes into operation for the purposes of the functions, or under the authority, of the Coroner.
- (2) If DHSC receives notice in writing from the Coroner that a tissue sample specified in the notice and removed from the body of a deceased person so specified is no longer required for the purposes of the functions of the Coroner, on the date of the notice the tissue sample becomes, and accordingly falls to be retained as, part of the medical records of the deceased person.

## **56 Use of tissue sample which has become part of deceased’s medical records**

S2006/4/39

Where, by virtue of notice under section 55(2) a tissue sample becomes part of the medical records of a deceased person, it may —

- (a) be used for the purposes of—
  - (i) providing information about or confirming the cause of death;
  - (ii) investigating the effect and efficacy of any medical or surgical intervention carried out on the person;
  - (iii) obtaining information which may be relevant to the health of any other person (including a future person);
  - (iv) audit;
- (b) be used for the purposes of education, training or research, if use for the purpose in question is authorised in accordance with section 58, 59, 60, 61 or 62 as the case requires.

**57 Use of organ no longer required for Coronial purposes**

S2006/4/40

- (1) This section applies to an organ removed from the body of a deceased person during an examination of the body carried out on or after the day on which this section comes into force for the purposes of the functions, or under the authority, of the Coroner.
- (2) The organ may be retained and used for the purposes of education, training or research if—
  - (a) DHSC receives notice in writing from the Coroner that an organ specified in the notice and removed from the body of a deceased person so specified is no longer required for the purposes of the functions of the Coroner;
  - (b) the subsequent use of the organ for the purpose in question is authorised in accordance with section 58, 59, 60, 61 or 62 as the case requires; and
  - (c) where the purpose in question is research, the research is approved in writing by such person (or persons), or group (or groups) of persons, as the Department may specify by order under this subsection.

**58 Authorisation of use, etc., after examination: adult**

S2006/4/42

- (1) An adult may authorise—
  - (a) use of a tissue sample removed from the adult's body after the adult's death during an examination of the body for the purposes of the functions, or under the authority, of the Coroner;
  - (b) retention and use of an organ removed from the adult's body after the adult's death during such an examination,for one or more of the purposes referred to in section 56(b).
- (2) Authorisation by virtue of subsection (1)—
  - (a) must be in writing and—
    - (i) signed by the adult; or
    - (ii) subject to subsection (4), if the adult is blind or unable to write signed by another adult (a "signatory") on the adult's behalf and witnessed by one witness;
  - (b) may be withdrawn in writing—
    - (i) signed by the adult; or
    - (ii) subject to subsection (4), if the adult is blind or unable to write signed by another adult (a "signatory") on the adult's behalf and witnessed by one witness.

- (3) Authorisation by virtue of subsection (1), or withdrawal of such authorisation, which is signed by a signatory on behalf of the adult by virtue of subsection (2)(a)(ii) or (b)(ii) must contain a statement signed by both the signatory and the witness in the presence of the adult and of each other that the adult, in the presence of them both, expressed the intention to give the authorisation or, as the case requires, withdraw the authorisation and requested the signatory to sign the authorisation or, as the case requires, the withdrawal on behalf of the adult.
- (4) Nothing in subsection (2)(a)(ii) or (b)(ii) prevents an adult who is blind from signing an authorisation by virtue of subsection (1) in accordance with subsection (2)(a)(i) or a withdrawal of authorisation in accordance with subsection (2)(b)(i).

## **59 Authorisation of use etc. after examination: person in qualifying relationship to adult**

S2006/4/43

- (1) A person who, immediately before the death of an adult stood in a qualifying relationship to a deceased adult may authorise one or more of the matters referred to in section 58(1) in relation to the deceased adult if there is in force immediately before the adult's death no authorisation by the adult by virtue of that section of any of the matters referred to in it.
- (2) Authorisation by virtue of subsection (1) must—
  - (a) be in writing signed by the person giving the authorisation and witnessed by one witness;
  - (b) state that the person giving the authorisation has no actual knowledge that the adult was unwilling for the matter in question to be authorised (for the purpose in question).
- (3) Authorisation by virtue of subsection (1) may be withdrawn in writing signed by the person who gave it and witnessed by one witness.
- (4) If the person referred in subsection (1) is blind or unable to write, authorisation by virtue of subsection (2) or withdrawal of authorisation by virtue of subsection (3) may be signed by another adult (a "signatory") on that person's behalf and if it is so signed it must be witnessed by one witness.

## **60 Authorisation of use etc. after examination: child 12 years of age or over**

S2006/4/44

- (1) A child who is 12 years of age or over may authorise—
  - (a) use of a tissue sample removed from the child's body after the child's death during an examination of the body for the purposes of the functions, or under the authority, of the Coroner;

- (b) retention and use of an organ removed from the child's body after the child's death during such an examination,
- for one or more of the purposes referred to in section 56(b).
- (2) Authorisation by virtue of subsection (1)—
- (a) must be in writing—
- (i) signed by the child and witnessed by 2 witnesses; or
- (ii) subject to subsections (3) and (4), if the child is blind or unable to write signed by an adult (a “signatory”) on the child's behalf and witnessed by one witness;
- (b) may be withdrawn in writing—
- (i) signed by the child; or
- (ii) subject to subsections (3) and (4), if the child is blind or unable to write signed by an adult (a “signatory”) on the child's behalf and witnessed by one witness.
- (3) Authorisation by virtue of subsection (1), or withdrawal of such authorisation, which is signed by a signatory on behalf of the child by virtue of subsection (2)(a)(ii) or (b)(ii) must contain a statement signed by both the signatory and the witness in the presence of the child and of each other that the child, in the presence of them both, expressed the intention to give or withdraw the authorisation and requested the signatory to sign the authorisation or, as the case requires, the withdrawal on behalf of the child.
- (4) Authorisation by virtue of subsection (1) which is signed by a signatory on behalf of a child by virtue of subsection (2)(a)(ii) must contain or be accompanied by certification in writing signed by the signatory that, in the opinion of the signatory, the child understands the effect of the authorisation and is not acting under undue influence in giving it.
- (5) Nothing in subsection (2)(a)(ii) or (b)(ii) prevents a child who is blind from signing an authorisation by virtue of subsection (1) in accordance with subsection (2)(a)(i) or a withdrawal of authorisation in accordance with subsection (2)(b)(i).
- (6) Each witness to authorisation by a child by virtue of subsection (1) (whether it is signed by the child or by a signatory on behalf of the child), must at the time of witnessing certify (in writing signed by the witness) that, in the opinion of the witness, the child understands the effect of the authorisation and is not acting under undue influence in giving it.

## **61 Authorisation of use etc. after examination: person with parental responsibility for child 12 years of age or over**

S2006/4/45

- (1) A person who immediately before the death of a child who died 12 years of age or over had parental responsibility in relation to the child (other

than DHSC) may authorise one or more of the matters referred to in section 60(1) in relation to the deceased child if there is in force immediately before the death no authorisation by the child by virtue of that section of any of the matters referred to in it.

- (2) Authorisation by virtue of subsection (1) must—
  - (a) be in writing signed by the person who gives the authorisation in accordance with that subsection and witnessed by 2 witnesses;
  - (b) state that the person giving the authorisation has no actual knowledge that the child was unwilling for the matter in question to be authorised (for the purpose in question).
- (3) Authorisation by virtue of subsection (1) may be withdrawn in writing signed by the person who gave the authorisation in accordance with that subsection and witnessed by 2 witnesses.
- (4) If the person referred in subsection (1) is blind or unable to write, authorisation by virtue of subsection (2) or withdrawal of authorisation by virtue of subsection (3) may be signed by another adult (a “signatory”) on that person’s behalf and if it is so signed it must be witnessed by 2 witnesses.

## **62 Authorisation of use etc. after examination: person with parental responsibility for child under 12 years of age**

S2006/4/46

- (1) A person who immediately before the death of a child who died under 12 years of age had parental responsibility for the child (other than DHSC) may authorise one or more of the matters referred to in section 60(1) as respects the deceased child.
- (2) Authorisation by virtue of subsection (1)—
  - (a) must be in writing signed by the person who gives the authorisation in accordance with that subsection and witnessed by 2 witnesses;
  - (b) may be withdrawn in writing so signed and witnessed by one witness.
- (3) If the person referred in subsection (1) is blind or unable to write, an authorisation or its withdrawal may be signed by an adult (a “signatory”) on that person’s behalf and if it is so signed it must be witnessed by 2 witnesses.

## **63 Use of tissue sample removed before day on which section 55 comes into operation**

S2006/4/47

Tissue sample removed from the body of a deceased person (or from an organ which was removed from the body) during an examination of the body carried

out before the day on which section 55 comes into force for the purposes of the functions, or under the authority, of the Coroner and held immediately before that day for use for any of the purposes referred to in paragraph (b) of section 56 (whether or not held immediately before that day also for the purposes of the functions of the Coroner) may be retained and used for any of the purposes referred to in that paragraph (whether or not it is retained and used also for the purposes of the functions of the Coroner).

#### **64 Use of organ removed before day on which section 57 comes into operation**

S2006/4/48

- (1) An organ removed from the body of a deceased person during an examination of the body carried out before the day on which section 57 comes into force for the purposes of the functions, or under the authority, of the Coroner and held immediately before that day for use for the purposes of existing approved research (whether or not held immediately before that day also for the purposes of the functions of the Coroner) may be retained and used for the purposes of the existing approved research or for the purposes of education, training or new approved research (whether or not it is retained and used also for the purposes of the functions of the Coroner).
- (2) In subsection (1)—
  - (a) “existing approved research” means research approved before the day on which section 57 comes into force;
  - (b) “new approved research” means research approved on or after that day,  
  
by such person (or persons), or group (or groups) of persons, as the Department may specify by order under this section.

#### **65 Conditions attached to authorisation**

S2006/4/49

- (1) Authorisation—
  - (a) by virtue of section 8, 9, 10, 11, 46, 47, 48, 49 or 50 of removal and use of a part of a body for a purpose mentioned in section 40(d);
  - (b) by a person nominated by virtue of section 47(1) of a matter referred to in section 46(1);
  - (c) by virtue of section 47(2) of a matter referred to in section 46(1);
  - (d) by a person nominated by virtue of section 49(1) of a matter referred to in section 48(1);
  - (e) by virtue of section 49(2) or 50(1) of a matter referred to in section 48(1);
  - (f) by virtue of section 59(1) of a matter referred to in section 58(1);

- (g) by virtue of section 61(1) or 62(1) of a matter referred to in section 60(1),
- may be accompanied by a request that the matter authorised is to be carried out subject to conditions specified in the authorisation.
- (2) Where a request is made by virtue of subsection (1), the matter must be carried out (in so far as it is reasonably practicable to do so) in accordance with the conditions.

## PART 5 — MISCELLANEOUS AND GENERAL

### DIVISION 1: MISCELLANEOUS

#### 66 Preservation for transplantation

P2004/30/43

- (1) Where part of a body lying in a hospital, nursing home or other institution is or may be suitable for use for transplantation, it is lawful for the person having the control and 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—
- (a) to 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 consent making removal of the part for transplantation lawful has not been, and will not 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 this subsection to act under the authority.
- (5) An activity done with authority under subsection (1) is to be treated —
- (a) for the purposes of Part 2, as not being an activity to which section 7(1) applies;
- (b) for the purposes of Part 3, as not being an activity to which section 20 applies.
- (6) Section 16(2) applies for the purposes of an act done on authority under subsection (1) as it applies to an act done on authority under section 7.



- (7) In this section, “body” means the body of a deceased person.

## 67 Surplus tissue

P2004/30/44 and drafting

- (1) It is lawful for material to which subsection (2) or (3) applies to be dealt with as clinical waste.
- (2) This subsection applies to any material which consists of or includes human cells and which has come from a person’s body in the course of—
- (a) the person—
    - (i) receiving medical treatment,
    - (ii) undergoing diagnostic testing, or
    - (iii) participating in research; or
  - (b) a post-mortem examination.
- (3) This subsection applies to any relevant organ or tissue which —
- (a) has come from a human body, and
  - (b) ceases to be used, or stored for use, for a purpose specified in Schedule 1.
- (4) This section shall not be read as making unlawful anything which is lawful apart from this section.
- (5) For the avoidance of doubt, this section is subject to directions under section 12(2) of the *Abortion Reform Act 2019* (directions in relation to disposal of the products of conception).

## 68 Non-consensual analysis of DNA

P2004/30/45

- (1) A person (“P”) commits an offence if —
- (a) P has any bodily material intending —
    - (i) that any human DNA in the material be analysed without qualifying consent, and
    - (ii) that the results of the analysis be used otherwise than for an excepted purpose,
  - (b) the material is not of a kind excepted under subsection (2), and
  - (c) P does not reasonably believe the material to be of a kind so excepted.
- (2) Bodily material is excepted if —
- (a) it is material which has come from the body of a person who died before the day on which this section comes into operation and at least 100 years have elapsed since the date of the person’s death,

- (b) it is an existing holding and the person who has it is not in possession, and not likely to come into possession, of information from which the individual from whose body the material has come can be identified, or
- (c) it is an embryo outside the human body.

Maximum penalty for an offence under this section —

- (a) (summary) a level 5 fine or 12 months' custody;
  - (b) (on information) 3 years' custody.
- (3) Schedule 3 (which makes provision for the interpretation of “**qualifying consent**” and “**use for an excepted purpose**” in subsection (1)(a)) has effect.
- (4) In this section (and Schedule 3) —
- “**bodily material**” means material which —
- (a) has come from a human body, and
  - (b) consists of or includes human cells;

“**existing holding**” means bodily material held immediately before the day on which this section comes into force.

## DIVISION 2: GENERAL

### 69 Powers of inspection, entry, search and seizure

Schedule 4 (which makes provision about powers of inspection, entry, search and seizure for the purposes of this Act) has effect.

### 70 Prosecutions

Drafting

Proceedings for an offence under this Act may be instituted only by or with the consent of the Attorney General.

### 71 Amendment to reflect provisions of, or under, Parts 2 and 3 of the 2004 Act

Drafting

- (1) The Department may by order amend this Act in order to secure that, so far as the Department considers appropriate, this Act contains or enables the making of provision corresponding to—
- (a) the provisions of Parts 2 and 3 of the 2004 Act as they have effect from time to time in England; and
  - (b) any provision made under either of those Parts (including codes of practice made by the Human Tissue Authority established by section 13 of the 2004 Act); and

- (c) any provision having effect in England in respect of activities involving human tissue.

This is subject to the following provisions of this section.

- (2) An order under subsection (1) may amend or repeal any Manx enactment, including one contained in this Act, if it is inconsistent with, or unnecessary in consequence of, the provision made by the order.
- (3) Before making an order under subsection (1), the Department must consult NHSBT and such other persons as it considers appropriate.
- (4) The provision falling within subsection (1)(c) includes, in particular —
  - (a) the Human Tissue (Quality and Safety for Human Application) Regulations 2007<sup>11</sup>, and
  - (b) the Quality and Safety of Organs Intended for Transplantation Regulations 2012<sup>12</sup>,

(both of Parliament) as those Regulations have effect from time to time in in England.

## 72 Orders and regulations

Section 30 of the *Legislation Act 2015* (Tynwald procedure — approval required) applies to any order or regulations under this Act, except an order under section 2 or 25.

## 73 Financial provisions

P2004/30/55

There shall be paid out of the General Revenue —

- (a) any expenditure incurred by the Department or DHSC in consequence of this Act, and
- (b) any increase attributable to this Act in the sums payable out of money so provided under any other enactment.

## 74 Consequential amendments

Schedule 5 (consequential amendments) has effect.

## 75 Consultation

The Department must consult DHSC before —

- (a) making regulations or orders,
- (b) giving directions, or
- (c) issuing a code of practice,

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<sup>11</sup> S.I. 2007/1523, relevantly amended by S.I. 2014/2883, 2018/335 and 2019/481.

<sup>12</sup> S.I. 2012/1501, relevantly amended by S.I. 2014/1459.

under this Act.

## **76 Repeals**

The *Human Tissue Act 1986* and the *Human Organ Transplants Act 1993* are repealed.

**SCHEDULE 1**  
**SCHEDULED PURPOSES**

Section 7

**PART 1 – PURPOSES REQUIRING CONSENT: GENERAL**

1. Anatomical examination.
2. Determining the cause of death.
3. Establishing after a person's death the efficacy of any drug or other treatment administered to that person.
4. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).
5. Public display.
6. Research in connection with disorders, or the functioning, of the human body.
7. Transplantation.

**PART 2 – PURPOSES REQUIRING CONSENT: DECEASED PERSONS**

8. Clinical audit.
9. Education or training relating to human health.
10. Performance assessment.
11. Public health monitoring.
12. Quality assurance.

## SCHEDULE 2

## LICENCES FOR THE PURPOSES OF SECTION 20

[Section 20]

**1 Power to grant licence**

P2004/30/Sch. 3/para. 1

The Department may on application grant a licence for the purposes of section 20.

**2 Characteristics of licence**

P2004/30/Sch. 3/para. 2

- (1) A licence shall not authorise the carrying-on of more than one activity to which section 20 applies.
- (2) A licence shall —
  - (a) specify the premises where the licensed activity is authorised to be carried on, and
  - (b) designate an individual as the person under whose supervision the licensed activity is authorised to be carried on.
- (3) A licence shall not authorise the licensed activity to be carried on —
  - (a) on premises at different places, or
  - (b) under the supervision of more than one individual.
- (4) It shall be a condition of a licence —
  - (a) that the licensed activity shall be carried on only on the premises specified in the licence;
  - (b) that the licensed activity shall be carried on only under the supervision of the individual designated in the licence as the person under whose supervision it is authorised to be carried on;
  - (c) that such information about such matters relating to the carrying-on of the licensed activity as may be specified in directions shall be recorded in such form as may be so specified;
  - (d) that any record made for the purposes of the condition in paragraph (c) shall be kept until the end of such period as may be specified in directions;
  - (e) that there shall be provided to such person and at such intervals as may be specified in directions —
    - (i) such copies of, or extracts from, any record to which the condition in paragraph (d) relates, and
    - (ii) such other information, as may be so specified;

- (f) that there shall be paid to the Department at such times as may be specified in directions sums of such amount as may be so specified in respect of its costs in connection with superintending compliance with the terms of licences.
- (5) Directions for the purposes of sub-paragraph (4) may be given in relation to licences generally, licences of a particular description or a particular licence.

### 3 Licences authorising storage of anatomical specimens

P2004/30/Sch. 3/para. 3

- (1) This paragraph applies to a licence authorising the storage of anatomical specimens.
- (2) It shall be a condition of a licence to which this paragraph applies that storage at the premises specified in the licence of the body of a deceased person for use for the purpose of anatomical examination shall not begin before that body's storage there for use for that purpose has been authorised in writing by —
  - (a) the designated individual, or
  - (b) an individual who has the Department's permission to give such authorisation (see paragraph 12).
- (3) It shall be a condition of a licence to which this paragraph applies that any anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the designated individual to have the specimen in his or her possession.
- (4) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give authority for the purposes of the condition in sub-paragraph (3) only if he or she is satisfied —
  - (a) that the person to whom authority is given is a suitable person to have the specimen in his possession, and
  - (b) that that person intends to use the specimen only for the purpose of education, training or research.
- (5) It shall be a condition of a licence to which this paragraph applies that any authority given for the purposes of the condition in sub-paragraph (3) shall specify —
  - (a) the person to whom the authority is given,
  - (b) the specimen to which the authority relates,
  - (c) the purpose for which the specimen may be used, and
  - (d) the duration of the authority.
- (6) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give such notice of any authorisation for the

purposes of the condition in sub-paragraph (3) as may be specified in directions.

- (7) It shall be a condition of a licence to which this paragraph applies that such information about authorisations for the purposes of the condition in sub-paragraph (3) as may be specified in directions shall be recorded in such form as may be so specified.

#### **4 Licence authorising storage of a dead body or relevant organ or tissue from a human body**

- (1) This paragraph applies to a licence authorising the activity mentioned in section 20(2)(e).
- (2) It shall be a condition of a licence to which this paragraph applies that any former anatomical specimen which is stored at the premises specified in the licence shall be released from storage at the premises only into the possession of a person who is authorised in writing by the designated individual to have the specimen in his or her possession.
- (3) The condition in sub-paragraph (2) does not apply to the release from storage of a specimen for the purpose of its decent disposal.
- (4) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give authority for the purposes of the condition in sub-paragraph (2) only if satisfied —
- (a) that the person to whom authority is given is a suitable person to have the specimen in his or her possession, and
  - (b) that that person intends to use the specimen only for the purpose of education, training or research.
- (5) It shall be a condition of a licence to which this paragraph applies that any authority given for the purposes of the condition in sub-paragraph (2) shall specify —
- (a) the person to whom the authority is given,
  - (b) the specimen to which the authority relates,
  - (c) the purpose for which the specimen may be used, and
  - (d) the duration of the authority.
- (6) It shall be a condition of a licence to which this paragraph applies that the designated individual shall give such notice of any authorisation for the purposes of the condition in sub-paragraph (2) as may be specified in directions.
- (7) It shall be a condition of a licence to which this paragraph applies that such information about authorisations for the purposes of the condition in sub-paragraph (2) as may be specified in directions shall be recorded in such form as may be so specified.



## 5 Power to impose conditions

P2004/30/Sch. 3/para 5

The Department may grant a licence subject to such further conditions as it thinks fit.

## 6 Pre-conditions to grant of licence

P2004/30/Sch. 3/para 6

- (1) The Department may not grant a licence in pursuance of an application unless the following requirements are met.
- (2) The proposed designated individual must —
  - (a) be the applicant for the licence, or
  - (b) consent to the application for the licence.
- (3) The Department must be satisfied that the proposed designated individual —
  - (a) is a suitable person to supervise the activity to be authorised by the licence, and
  - (b) will perform the duty under section 22.
- (4) Where the applicant for the licence is not the proposed designated individual, the Department must be satisfied that the applicant is a suitable person to be the holder of the licence.
- (5) The Department must be satisfied that the premises in respect of which the licence is to be granted are suitable for the activity to be authorised by the licence.
- (6) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by —
  - (a) the applicant for the licence, and
  - (b) where different, the proposed designated individual.
- (7) In this paragraph, references to the proposed designated individual are to the individual whom the application proposes the licence designate as the person under whose supervision the activity to be authorised by the licence is to be carried on.

## 7 Revocation of a licence

P2004/30/Sch 3, para 7

- (1) The Department may revoke a licence on application by —
  - (a) the holder of the licence, or
  - (b) the designated individual.
- (2) The Department may revoke a licence otherwise than on an application under sub-paragraph (1) if —

- (a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading,
  - (b) it is satisfied that the designated individual has failed to discharge, or is unable because of incapacity to discharge, the duty under section 22,
  - (c) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,
  - (d) it ceases to be satisfied that the person to whom the licence is granted is a suitable person to be the holder of the licence,
  - (e) it ceases to be satisfied that the designated individual is a suitable person to supervise the licensed activity,
  - (f) the designated individual dies,
  - (g) it is satisfied that there has been any other material change of circumstances since the licence was granted, or
  - (h) it is not satisfied that any third country premises are suitable for carrying out activities in a manner which secures that tissues or cells imported from a third country by an importing licence holder meet standards of quality and safety equivalent to those laid down in the 2007 Regulations.
- (3) For the purposes of sub-paragraph (2)(h), “importing licence holder” , “third country” and “third country premises” have the same meaning as in the 2007 Regulations.

## 8 Variation of a licence

P2004/30/Sch. 3/para. 8

- (1) The Department may on application by the holder of a licence vary the licence so as to substitute another individual for the designated individual if—
- (a) the application is made with the consent of the other individual, and
  - (b) the authority is satisfied that the other individual is a suitable person to supervise the licensed activity.
- (2) The Department may vary a licence on application by—
- (a) the holder of the licence, or
  - (b) the designated individual.
- (3) The Department may vary a licence without an application under sub-paragraph (2) if it has power to revoke the licence under paragraph 7(2).
- (4) The powers under sub-paragraphs (2) and (3) do not extend to making the kind of variation mentioned in sub-paragraph (1).

- (5) The Department may vary a licence without an application under sub-paragraph (2) by —
  - (a) removing or varying a condition of the licence, or
  - (b) adding a condition to the licence.
- (6) The powers conferred by this paragraph do not extend to the conditions required by paragraphs 2(4), 3 and 4.

## 9 Suspension of licences

P2004/30/Sch. 3/para. 9

- (1) Where the Department —
  - (a) has reasonable grounds to suspect that there are grounds for revoking a licence, and
  - (b) is of the opinion that the licence should immediately be suspended,it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.
- (2) The Department may continue suspension under sub-paragraph (1) by giving a further notice under that sub-paragraph.
- (3) Notice under sub-paragraph (1) shall be given to the designated individual or, where the designated individual has died or appears to the Department to be unable because of incapacity to discharge the duty under section 22 —
  - (a) to the holder of the licence, or
  - (b) to some other person to whom the licence applies.
- (4) Subject to sub-paragraph (5), a licence shall be of no effect while a notice under sub-paragraph (1) is in force.
- (5) An application may be made under paragraph 7(1) or 8(1) or (2) notwithstanding the fact that a notice under sub-paragraph (1) is in force.

## 10 Procedure in relation to licensing decisions

- (1) Before making a decision —
  - (a) to refuse an application for the grant, revocation or variation of a licence, or
  - (b) to grant an application for a licence subject to a condition under paragraph 5,the Department must give the applicant notice of the proposed decision and of the reasons for it.
- (2) Before making a decision under paragraph 7(2) or (5) or 8(3), the Department must give notice of the proposed decision and of the reasons for it to —

- (a) the holder of the licence, and
  - (b) where different, the designated individual.
- (3) A person (“P”) to whom notice under sub-paragraph (1) or (2) is given has the right to require the Department to give P an opportunity to make representations of one of the following kinds about the proposed decision, namely —
- (a) oral representations by P, or a person acting on P’s behalf;
  - (b) written representations by P.
- (4) The right under sub-paragraph (3) is exercisable by giving the Department notice of exercise of the right before the end of the period of 28 days beginning with the day on which the notice under sub-paragraph (1) or (2) was given.
- (5) The Department may by regulations make such additional provision about procedure in relation to the carrying out of functions under this Schedule as it thinks fit.

## 11 Notification of licensing decisions

- (1) In the case of a decision to grant a licence, the Department must give notice of the decision to —
- (a) the applicant, and
  - (b) the person who is to be the designated individual.
- (2) In the case of a decision to revoke a licence, the Department must give notice of the decision to —
- (a) the holder of the licence, and
  - (b) the designated individual.
- (3) In the case of a decision to vary a licence on an application under paragraph 8(1), the Department must give notice of the decision to —
- (a) the holder of the licence, and
  - (b) the person who is to be the designated individual.
- (4) In the case of any other decision to vary a licence, the Department must give notice of the decision to —
- (a) the holder of the licence, and
  - (b) the designated individual.
- (5) In the case of a decision to refuse an application for the grant, revocation or variation of a licence, the Department must give notice of the decision to the applicant.
- (6) Subject to sub-paragraph (7), a notice under sub-paragraph (2), (4) or (5) shall include a statement of the reasons for the decision.

- (7) In the case of a notice under sub-paragraph (2) or (4), the notice is not required to include a statement of the reasons for the decision if the decision is made on an application under paragraph 7(1) or 8(2).

## **12 Licences authorising storage of anatomical specimens: supplemental**

- (1) This paragraph applies to a licence authorising the storage of anatomical specimens.
- (2) The reference to the Department's permission in the condition of the licence required by paragraph 3(2) ("the authorisation condition") is to —
- (a) permission granted by the Department on an application made, in conjunction with the application for the licence, by —
- (i) the applicant for the licence, or
- (ii) the person who, within the meaning of paragraph 6, is the proposed designated individual, or
- (b) permission granted by the Department on application by —
- (i) the holder of the licence, or
- (ii) the designated individual.
- (3) The Department may grant permission to an individual for the purposes of the authorisation condition only if it is satisfied that the individual is a suitable person to give authorisation under that condition.
- (4) The Department may revoke permission granted to an individual for the purposes of the authorisation condition —
- (a) on application by the individual, the designated individual or the holder of the licence, or
- (b) if it ceases to be satisfied that the individual is a suitable person to give authorisation under that condition.
- (5) Before refusing an application for the grant or revocation of permission, the Department shall give the applicant notice of the proposed refusal and of the reasons for it.
- (6) Before revoking permission under sub-paragraph (4)(b), the Department shall give notice of the proposed revocation and of the reasons for it —
- (a) to the individual concerned, and
- (b) to the designated individual and, where different, the holder of the licence.
- (7) Paragraph 10(3) and (4) shall apply in relation to notice under sub-paragraph (5) or (6) as to notice under paragraph 10(1).
- (8) In the case of a decision to refuse an application for the grant or revocation of permission, the Department must give notice of the decision to the applicant.

- (9) In the case of a decision to grant or revoke permission, the Department must give notice of the decision —
- (a) to the individual concerned, and
  - (b) to the designated individual and, where different, the holder of the licence.
- (10) Notice under sub-paragraph (8), and notice under sub-paragraph (9) of revocation under sub-paragraph (4)(b), shall include a statement of the reasons for the refusal or revocation.
- (11) Where the Department —
- (a) has reasonable grounds to suspect that there are grounds for revoking permission granted to an individual for the purposes of the authorisation condition, and
  - (b) is of the opinion that the permission should immediately be suspended,
- it may by notice suspend the permission for such period not exceeding three months as may be specified in the notice.
- (12) The Department may continue suspension under sub-paragraph (11) by giving a further notice under that sub-paragraph.
- (13) Notice under sub-paragraph (11) must be given to —
- (a) the individual concerned, and
  - (b) the designated individual and, where different, the holder of the licence.

### 13 Applications under this Schedule

- (1) The Department may by regulations make provision about applications under this Schedule, Schedule 1 to the 2007 Regulations and Schedule 1 to the 2012 Regulations and may, in particular, make provision about —
- (a) the form and content of such an application,
  - (b) the information to be supplied with such an application, and
  - (c) procedure in relation to the determination of such an application.
- (2) An application under this Schedule shall be accompanied by such fee (if any) as the Department may determine.

## SCHEDULE 3

## SECTION 68: SUPPLEMENTARY

## Section 68

## PART 1 - QUALIFYING CONSENT

**1 Introductory**

P2004/30/Sch. 4/para. 1

This Part of this Schedule makes provision for the interpretation of “qualifying consent” in section 68(1)(a)(i).

**2 Qualifying consent**

P2004/30/Sch. 4/para. 2

- (1) In relation to analysis of DNA manufactured by the body of a person who is alive, “qualifying consent” means that person’s consent, except where sub-paragraph (2) applies.
- (2) Where —
  - (a) the person is a child (“C”),
  - (b) neither a decision of C to consent, nor a decision of C not to consent, is in force, and
  - (c) either C is not competent to deal with the issue of consent or, though C is competent to deal with that issue, C fails to do so,“qualifying consent” means the consent of a person who has parental responsibility for C.
- (3) In relation to analysis of DNA manufactured by the body of a person who has died an adult (“A”), “qualifying consent” means —
  - (a) if a decision of A’s to consent, or a decision of A’s not to consent, was in force immediately before A died, A’s consent;
  - (b) if paragraph (a) does not apply, the consent of a person who stood in a qualifying relationship to A immediately before A died.
- (4) In relation to analysis of DNA manufactured by the body of a person who has died a child (“C”), “qualifying consent” means —
  - (a) if a decision of C’s to consent, or a decision of C’s not to consent, was in force immediately before C died, C’s consent;
  - (b) if paragraph (a) does not apply —
    - (i) the consent of a person who had parental responsibility for C immediately before C died, or

- (ii) where no person had parental responsibility for C immediately before C died, the consent of a person who stood in a qualifying relationship to C at that time.

## PART 2 - USE FOR AN EXCEPTED PURPOSE

### 3 Introductory

P2004/30/Sch. 4/para. 4

This Part of this Schedule makes provision for the interpretation of “use for an excepted purpose” in section 68(1)(a)(ii).

### 4 Purposes of general application

P2004/30/Sch. 4/para. 5

- (1) Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose —
  - (a) the medical diagnosis or treatment of the person whose body manufactured the DNA;
  - (b) purposes of functions of a Coroner (including those in connection with the investigation of deaths);
  - (c) the prevention or detection of crime;
  - (d) the conduct of a prosecution;
  - (e) purposes of national security (whether of the Island or the United Kingdom);
  - (f) implementing an order or direction of a court or tribunal, including one outside the Island.
- (2) For the purposes of sub-paragraph (1)(c), detecting crime shall be taken to include —
  - (a) establishing by whom, for what purpose, by what means and generally in what circumstances any crime was committed, and
  - (b) the apprehension of the person by whom any crime was committed;and the reference in sub-paragraph (1)(c) to the detection of crime includes any detection outside the Island of any crime or suspected crime.
- (3) In sub-paragraph (1)(d), the reference to a prosecution includes a prosecution brought in respect of a crime in a country or territory outside the Island.
- (4) In this paragraph, a reference to a crime includes a reference to any conduct which —
  - (a) constitutes one or more criminal offences (whether under the law of the Island or a country or territory outside the Island),



- (b) is, or corresponds to, conduct which, if it all took place in the Island, would constitute one or more criminal offences, or
  - (c) constitutes one or more service offences within the meaning of the Armed Forces Act 2006 (as that Act of Parliament extends to the Island)<sup>13</sup>.
- (5) Sub-paragraph (1)(f) shall not be taken to confer any power to make orders or give directions.

## 5 DNA analysis results for research

P2004/30/Sch. 4 para 6

- (1) Use of the results of an analysis of DNA for the purpose of research in connection with disorders, or the functioning, of the human body is use for an excepted purpose if the bodily material concerned is the subject of an order under sub-paragraph (2).
- (2) The Department may by regulations specify circumstances in which the High Court may order that this paragraph apply to bodily material.

## 6 DNA analysis results: existing holdings

P2004/30/Sch. 4, para 7

Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose if the bodily material concerned is an existing holding —

- (a) clinical audit;
- (b) determining the cause of death;
- (c) education or training relating to human health;
- (d) establishing after a person's death the efficacy of any drug or other treatment administered to him or her;
- (e) obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person);
- (f) performance assessment;
- (g) public health monitoring;
- (h) quality assurance;
- (i) research in connection with disorders, or the functioning, of the human body;
- (j) transplantation.

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<sup>13</sup> See section 384(2) of that Act.

**7 DNA analysis results: bodily material taken from a living person**

P2004/30/Sch. 3, para

Use of the results of an analysis of DNA for any of the following purposes is use for an excepted purpose if the bodily material concerned is from the body of a living person —

- (a) clinical audit;
- (b) education or training relating to human health;
- (c) performance assessment;
- (d) public health monitoring;
- (e) quality assurance.

**8 DNA analysis results to obtain scientific or medical information about donor**

(1) Use of the results of an analysis of DNA for the purpose of obtaining scientific or medical information about the person whose body manufactured the DNA is use for an excepted purpose if —

- (a) the bodily material concerned is the subject of a direction under sub-paragraph (2) or (3), and
- (b) the information may be relevant to the person for whose benefit the direction is given or order is made.

(2) If the Department is satisfied —

- (a) that bodily material has come from the body of a living person,
- (b) that it is not reasonably possible to trace the person from whose body the material has come (“the donor”),
- (c) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the purpose of obtaining scientific or medical information about the donor, and
- (d) that there is no reason to believe —
  - (i) that the donor has died,
  - (ii) that a decision of the donor to refuse 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,

it may direct that this paragraph apply to the material for the benefit of the other person.

(3) If the Department is satisfied —

- (a) that bodily material has come from the body of a living person,
- (b) that it is desirable in the interests of another person (including a future person) that DNA in the material be analysed for the

purpose of obtaining scientific or medical information about the person from whose body the material has come (“the donor”),

- (c) that reasonable efforts have been made to get the donor to decide whether to consent to the use of the material for that purpose,
- (d) that there is no reason to believe —
  - (i) that the donor has died,
  - (ii) that a decision of the donor to refuse to 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) that the donor has been given notice of the application for the exercise of the power conferred by this sub-paragraph,

it may direct that this paragraph apply to the material for the benefit of the other person.

## **9 DNA analysis on anonymised basis for medical research**

Use of the results of an analysis of DNA for the purpose of research in connection with disorders, or the functioning, of the human body is use for an excepted purpose if —

- (a) the bodily material concerned is from the body of a living person,
- (b) the research is ethically approved by the Department, and
- (c) the analysis is to be 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 individual from whose body the material has come can be identified.

## **10 Purpose authorised under section 7**

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 the Island, for that purpose of the bodily material concerned is authorised by section 7(1).

## **11 Purposes relating to DNA of adults who lack capacity to consent**

P2004/30/Sch. 4/para. 12

- (1) Use of the results of an analysis of DNA for a purpose specified under sub-paragraph (2) is use for an excepted purpose if —
  - (a) the DNA has been manufactured by the body of a person who has attained the age of 18 years and, under the law of the Island, lacks capacity to consent to analysis of the DNA, and
  - (b) neither a decision of that person to consent to analysis of the DNA for that purpose, nor a decision of that person not to consent to analysis of it for that purpose, is in force.

- (2) The Department may by regulations specify for the purposes of this paragraph purposes for which DNA may be analysed.

**12 Power to amend paragraphs 5, 7 and 8**

P2004/30/Sch. 4/para. 13

The Department may by order amend paragraph 5, 7 or 8 for the purpose of —

- (a) varying or omitting any of the purposes specified in that paragraph, or
- (b) adding to the purposes so specified.

**SCHEDULE 4****POWERS OF INSPECTION, ENTRY, SEARCH AND SEIZURE**

[Section 69]

**1 Inspection of statutory records**

P2004/30/Sch. 5/para. 1

- (1) A duly authorised person may require a person to produce for inspection any records which he is required to keep by, or by virtue of, this Act.
- (2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection —
  - (a) in a visible and legible form, or
  - (b) in a form from which they can readily be produced in a visible and legible form.
- (3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

**2 Entry and inspection of licensed premises**

P2004/30/Sch. 4/para. 2

- (1) A duly authorised person may at any reasonable time enter and inspect any premises in respect of which a licence is in force.
- (2) The power in sub-paragraph (1) is exercisable for purposes of the Department's functions in relation to licences.

**3 Entry and search in connection with suspected offence**

P2004/30/Sch. 4/para. 3

- (1) If a justice of the peace is satisfied on sworn information, that there are reasonable grounds for believing —
  - (a) that an offence under Part 2 or 3 is being, or has been, committed on any premises, and
  - (b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,the justice may, by signed warrant, authorise a duly authorised person to enter the premises, if need be by force, and search them.
- (2) The conditions referred to are —
  - (a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;

- (b) that the premises are unoccupied;
  - (c) that the occupier is temporarily absent;
  - (d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.
- (3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

#### 4 Execution of warrants

- (1) Entry and search under a warrant under paragraph 3 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.
- (2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.
- (3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall —
- (a) produce the warrant to the occupier, and
  - (b) give the occupier —
    - (i) a copy of the warrant, and
    - (ii) an appropriate statement.
- (4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall —
- (a) produce the warrant to that other person,
  - (b) give that other person—
    - (i) a copy of the warrant, and
    - (ii) an appropriate statement, and
  - (c) leave a copy of the warrant in a prominent place on the premises.
- (5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Department.
- (6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.
- (7) Where the premises in relation to which a warrant under paragraph 3 is executed are unoccupied or the occupier is temporarily absent, the person

executing the warrant shall, when leaving the premises, leave them as effectively secured as he or she found them.

## **5 Seizure in the course of inspection or search**

- (1) A duly authorised person entering and inspecting premises under paragraph 2 may seize anything on the premises which he or she has reasonable grounds to believe may be required for purposes of the Department's functions relating to the grant, revocation, variation or suspension of licences.
- (2) A duly authorised person entering and searching premises under a warrant under paragraph 3 may seize anything on the premises which he or she has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under Part 2 or 3.
- (3) Where a person has power under sub-paragraph (1) or (2) to seize anything, he or she may take such steps as appear to be necessary for preserving the thing or preventing interference with it.
- (4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.
- (5) Where by virtue of sub-paragraph (1) or (2) a person seizes anything, he or she must leave on the premises from which the thing was seized a statement giving particulars of what has been seized and stating that he or she has seized it.

## **6 Powers: supplementary**

- (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.
- (2) Power under this Schedule to inspect or search any premises includes, in particular —
  - (a) power to inspect any equipment found on the premises,
  - (b) power to inspect and take copies of any records found on the premises, and
  - (c) in the case of premises in respect of which a licence is in force, power to observe the carrying-on on the premises of the licensed activity.
- (3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

- (4) A person's right to exercise a power under this Schedule is subject to his or her producing evidence of his or her entitlement to exercise it, if required.
- (5) As soon as reasonably practicable after having exercised a power under this Schedule to inspect or search premises, the duly authorised person must —
  - (a) prepare a written report of the inspection or search, and
  - (b) give the appropriate person a copy.
- (6) In sub-paragraph (2), the “appropriate person” means —
  - (a) in relation to premises in respect of which a licence is in force, the designated individual ;
  - (b) in relation to any other premises, the occupier.

## 7 Enforcement

A person commits an offence if —

- (a) he or she fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 6(3), or
- (b) he or she intentionally obstructs the exercise of any right under this Schedule.

Maximum penalty (summary) a fine of level 5 on the standard scale.

## 8 Interpretation

In this Schedule, “**duly authorised person**”, in the context of any provision, means a person authorised by the Department to act for the purposes of that provision.



## SCHEDULE 5

## CONSEQUENTIAL AMENDMENTS

## Section 74

**1 Coroner of Inquests Act 1987**

- (1) The *Coroner of Inquests Act 1987* is amended as follows.
- (2) In section 14 (post-mortem examinations at an inquest), after subsection (2) there is inserted —
- “(3) Nothing in this section shall have effect to require a person to make a post-mortem examination if the making of the examination by him would contravene section 20(1) of the *Human Tissue and Organ Donation Act 2021* (under which a person may make a post-mortem examination only under the authority of a licence under that Act).”
- (3) In section 15 (post-mortem examination without inquest)—
- (a) renumber the existing text as subsection (1); and 7
- (b) after that subsection insert —
- “(2) No direction under subsection (1) above shall have effect to require a person to make a post-mortem examination if the making of the examination by him would contravene section 20(1) of the *Human Tissue and Organ Donation Act 2021* (under which a person may make a post-mortem examination only under the authority of a licence under that Act).”

**2 Police Powers and Procedures Act 1998**

- (1) The Police Powers and Procedures Act 1998 is amended as follows.
- (2) In Schedule 1A, after paragraph 13, insert —
- “13A Human Tissue and Organ Donation Act 2021**
- Each of the powers of seizure conferred by the provisions of paragraph 5(1) (seizure of material relevant to licensing functions) and (2) (seizure of evidence of offences) of Schedule 4 to the *Human Tissue and Organ Donation Act 2021*.”

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