STATUTORY INSTRUMENTS.

S.I. No. 198 of 2014

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) (AMENDMENT) REGULATIONS 2014

S.I. No. 198 of 2014

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) (AMENDMENT) REGULATIONS 2014

I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Implementing Directive 2012/25/EU of 9 October 2012[1] and for the purpose of giving further effect to Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010[2], hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Quality and Safety of Human Organs Intended for Transplantation) (Amendment) Regulations 2014.

(2) The Principal Regulations and these Regulations may be cited together as the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012 and 2014.

2. In these Regulations, "Principal Regulations" means the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012).

3. The Principal Regulations are amended, in the "Arrangement of Regulations" by inserting after "38. Summary proceedings may be brought by IMB" the following:

"Part 8

Organ Exchange Between Member States of the European Economic Area

39. Interpretation of this Part

40. Responsibility for functions under Directive 2012/25/EU

41. Common procedural rules

42. Information on organ and donor characterisation

43. Information to ensure the traceability of organs

44. Reporting of serious adverse events and reactions"

[1]OJ No. L 275, 10.10.2012, p. 27.
[2]OJ No. L 207, 6.8.2010, p. 14. As affected by Corrigendum (OJ No. L 243, 16.9.2010, p. 68).

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 9th May, 2014.

4. Regulation 2 of the Principal Regulations is amended—

(*a*) in the definition of "European organ exchange organisation", by deleting "of the European Union",

(*b*) by substituting for the definition of "Member State" the following definition:

"'Member State' means a State which is a contracting party to the Agreement on the European Economic Area signed in Oporto on 2 May 1992;", and

(*c*) in the definition of "transplantation centre", by inserting ", in the case of a transplantation centre in the State," after "transplantation of organs and".

5. Regulation 4 of the Principal Regulations is amended—

(*a*) in paragraph (2)(*a*), by substituting "11(1) and (4)" for "11(1)", and

(*b*) in paragraph (3)(*a*), by deleting "11(4),".

6. Regulation 15 of the Principal Regulations is amended by deleting paragraph (6).

7. Regulation 18 of the Principal Regulations is amended by deleting paragraph (6).

8. Regulation 19 of the Principal Regulations is amended by deleting paragraph (4).

9. Regulation 35(2)(*h*) of the Principal Regulations is amended by substituting "European Economic Area" for "European Union".

10. The Principal Regulations are amended by inserting after Part 7 the following Part:

"Part 8

ORGAN EXCHANGE BETWEEN MEMBER STATES OF THE EUROPEAN ECONOMIC AREA

Interpretation of this Part

39. In this Part—

'delegated body' means—

(i) a body to which tasks have been delegated in accordance with Regulation 4(5), or Article 17(1) of the Directive, or

(ii) a European organ exchange organisation to which tasks have been delegated in accordance with Regulation 29, or Article 21 of the Directive;

'Directive 2012/25/EU' means Commission Implementing Directive 2012/25/EU of 9 October 2012[1];

'Member State of destination' means the Member State to which the organ is sent for the purpose of transplantation;

'Member State of origin' means the Member State where the organ is procured with the purpose of transplantation;

'National donor identification number' means the identification code attributed to a donor in accordance with the identification system established pursuant to Regulation 18(2);

'National recipient identification number' means the identification code attributed to a recipient in accordance with the identification system established pursuant to Regulation 18(2);

'Specification of the organ' means—

(i) the anatomical description of an organ including: its type (e.g. heart, liver),

(ii) where applicable, its position (left or right) in the body, and

(iii) whether it is a whole organ or a part of an organ, mentioning the lobe or segment of the organ.

Responsibility for functions under Directive 2012/25/EU

40. (1) The HSE shall perform the functions of the competent authority under Articles 5, 6 and 7 of Directive 2012/25/EU.

(2) Where information is received by the HSE or the appropriate delegated body pursuant to Article 7 of Directive 2012/25/EU, the HSE or the appropriate delegated body shall forward it to the IMB.

Common procedural rules

41. (1) Information transmitted pursuant to this Part to another Member State shall:

(*a*) be transmitted in writing either electronically or by fax,

(*b*) be written in a language mutually understood by the sender and the addressee or, in absence thereof, in a mutually agreed language, or, in absence thereof, in English,

(*c*) be transmitted without undue delay,

(*d*) be recorded and capable of being made available upon request,

(*e*) indicate the date and time of the transmission,

(*f*) include the contact details of the person responsible for the transmission, and

(*g*) contain the following reminder:

"Contains personal data. To be protected against unauthorised disclosure or access.".

(2) Notwithstanding paragraph (1), in case of urgencies, information transmitted pursuant to this Part may be exchanged in a verbal form, in particular for exchanges pursuant to Articles 5 and 7 of Directive 2012/25/EU, and Regulations 42 and 44, provided that such verbal contacts are followed by a transmission in writing in accordance with those Articles and Regulations.

(3) Where information is transmitted to the State in accordance with Directive 2012/25/EU, the receiving authority or body shall ensure that the receipt of the information is confirmed to the sender, in accordance with the requirements set out in paragraph (1).

(4) The HSE or the appropriate delegated body, in conjunction with procurement organisations and transplantation centres, shall ensure that designated personnel—

(*a*) are available 24 hours a day and 7 days a week, for urgent situations, and

(*b*) are able to receive and transmit information pursuant to this Part and Directive 2012/25/EU without undue delay.

Information on organ and donor characterisation

42. (1) Where the State is to be the Member State of origin, prior to the organ being sent to the Member State of destination for the purpose of transplantation, the HSE, or the appropriate delegated body, shall transmit the information collected to characterise the procured organ and the donor, as specified in Regulation 15 and in the Annex to the Directive, to the competent authority or delegated body of the potential Member State of destination.

(2) Notwithstanding paragraph (1), where some of the information to be transmitted in accordance with that paragraph is not available at the time of the initial transmission and becomes available later, it shall be transmitted—

(*a*) by the HSE, or the appropriate delegated body, to the competent authority or delegated body of the Member State of destination, or

(*b*) directly by the procurement organisation to the transplantation centre in the Member State of destination,

in due time to allow for medical decisions.

(3) Procurement organisations and transplantation centres shall transmit to the HSE, or the appropriate delegated body, a copy of the information transmitted to or from them pursuant to this Regulation and Article 5 of Directive 2012/25/EU.

Information to ensure the traceability of organs

43. (1) Where the State is the Member State of origin, the HSE shall inform the competent authority or delegated body of the Member State of destination of—

(*a*) the specification of the organ,

(*b*) the national donor identification number of the donor,

(*c*) the date of procurement, and

(*d*) the name and contact details of the relevant procurement organisation.

(2) Where the State is the Member State of destination, the HSE shall inform the competent authority or delegated body of the Member State of origin of—

(*a*) the national recipient identification number of the recipient or, if the organ was not transplanted, the final use to which it was put,

(*b*) the date of transplantation, if applicable, and

(*c*) the name and contact details of the relevant transplantation centre.

Reporting of serious adverse events and reactions

44. (1) Where the HSE, or the appropriate delegated body, is notified of a serious adverse event or reaction that it suspects to relate to an organ that was received from another Member State, it shall immediately inform the competent authority or delegated body of the Member State of origin and transmit without undue delay to that competent authority or delegated body an initial report containing the information set out in Annex I to Directive 2012/25/EU, in so far as that information is available.

(2) Where the HSE, or the appropriate delegated body, is notified of a serious adverse event or reaction that it suspects to be related to a donor whose organs were sent to other Member States, it shall immediately inform the competent authorities or delegated bodies of each concerned Member State of destination and transmit to each of them an initial report containing the information set out in Annex I to Directive 2012/25/EU.

(3) When additional information becomes available following an initial report by the HSE, or the appropriate delegated body, under this Regulation, it shall be transmitted by the HSE, or the appropriate delegated body, without undue delay to the relevant competent authorities or delegated bodies.

(4) The HSE, or the appropriate delegated body, shall, within three months of transmitting an initial report pursuant to paragraph (1) or (2), transmit to the competent authorities or delegated bodies of all Member States of destination concerned, a common final report containing the information set out in Annex II of Directive 2012/25/EU, after collecting relevant information from all such Member States.

(5) Where the HSE, or the appropriate delegated body, receives an initial report from a competent authority or delegated body under Article 7 of Directive 2012/25/EU, it shall provide relevant information in a timely manner to that authority or delegated body of the Member State of origin."

L.S.

GIVEN under my Official Seal,
1 May 2014.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations give effect to Commission Implementing Directive 2012/25/EU of 9 October 2012 and give further effect to Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010.

These Regulations amend the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012.

These Regulations may be cited as the European Union (Quality and Safety of Human Organs Intended for Transplantation) (Amendment) Regulations 2014.

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STATUTORY INSTRUMENTS.

S.I. No. 325 of 2012

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012

S.I. No. 325 of 2012

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012

ARRANGEMENT OF REGULATIONS

Part 1

PRELIMINARY

PART 2

AUTHORISATION TO CARRY OUT PRESCRIBED ACTIVITIES

Part 3

QUALITY AND SAFETY OF ORGANS

S.I. No. 325 of 2012

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012

I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010[1], hereby make the following regulations:

Part 1

Preliminary

Citation

1. These Regulations may be cited as the European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012.

Interpretation

2. (1) In these Regulations—

"Act" means the Irish Medicines Board Act 1995, as amended by s. 197 of the Finance Act 1999 (No. 2 of 1999), Regulation 3 of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), Regulation 2 of the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. 576 of 2002), the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and the European Communities (Amendment of the Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007);

"authorisation" means an authorisation granted by the IMB in accordance with Regulation 6;

"authorised officer" means—

(*a*) a person appointed under Regulation 32, or

(*b*) an officer of Customs and Excise;

"Commission" means the Commission of the European Union;

"Data Protection Directive" means Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995[2], as amended by Regulation (EC)

[1]OJ No. L 207, 6.8.2010, p. 14. As affected by Corrigendum (OJ No. L 243, 16.9.2010, p. 68).
[2]OJ No. L 281, 23.11.1995, p. 31.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 31*st August*, 2012.

No. 1882/2003 of the European Parliament and of the Council of 29 September 2003[3]

"Directive" means Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010;

"disposal" means the final placement of an organ where it is not used for transplantation;

"donation" means donating organs for transplantation;

"donor" means a person who donates one or several organs, whether donation occurs during lifetime or after death;

"donor characterisation" means the collection of the relevant information on the characteristics of the donor needed to evaluate his or her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

"European organ exchange organisation" means a non-profit organisation, whether public or private, dedicated to national and cross-border organ exchange, in which the majority of its member countries are Member States of the European Union;

"framework for quality and safety" means the framework established by the HSE pursuant to Regulation 12;

"HSE" means the Health Service Executive established under section 6 of the Health Act 2004 (No. 42 of 2004);

"IMB" means the Irish Medicines Board established under section 3 of the Irish Medicines Board Act 1995 (No. 29 of 1995);

"Member State" means a Member State of the European Union;

"operating procedures" means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

"organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;

"organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

[3]OJ No. L 284, 31.10.2003, p. 1.

"prescribed activity" means any activity relating to the donation, testing, characterisation, procurement, preservation, transport or transplantation of organs intended for transplantation to the human body;

"preservation" means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation;

"procurement" means a process by which the donated organs become available;

"procurement organisation" means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the IMB in accordance with these Regulations;

"recipient" means a person who receives a transplant of an organ;

"responsible person" means a person who has been designated under Regulation 11 as the responsible person for a procurement organisation or transplantation centre;

"serious adverse event" means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation—

(*a*) that might lead to the transmission of a communicable disease,

(*b*) that might lead to death or life-threatening, disabling or incapacitating conditions for patients, or

(*c*) which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the living donor or in the recipient, that might be associated with any stage of the chain from donation to transplantation—

(*a*) that is fatal, life-threatening, disabling or incapacitating, or

(*b*) which results in, or prolongs, hospitalisation or morbidity;

"transplantation" means a process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient;

"transplantation centre" means a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs and is authorised to do so by the IMB in accordance with these Regulations;

"traceability" means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to—

(*a*) identify the donor and the procurement organisation,

(*b*) identify the recipient(*s*) at the transplantation centre(*s*), and

(*c*) locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ.

(2) In these Regulations, unless otherwise indicated—

(*a*) a word or expression which is also used in the Directive has the same meaning as it has in the Directive,

(*b*) a reference to a Regulation is to a Regulation of these Regulations,

(*c*) a reference to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, and

(*d*) a reference to the Schedule is to the Schedule to these Regulations.

Scope

3. (1) Subject to paragraph (2), the requirements of these Regulations shall apply to the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation into the human body.

(2) Where the organs referred to in paragraph (1) are used for research purposes, the requirements of these Regulations shall only apply where they are intended for transplantation into the human body.

(3) These Regulations shall apply without prejudice to the Data Protection Acts 1988 and 2003 in so far as those Acts transpose the Data Protection Directive.

Responsibility for functions under Directive

4. (1) The IMB shall perform—

(*a*) the functions of the State under Articles 5(2) and 9(4) of the Directive, and

(*b*) the functions of the competent authority under Articles 9(2), 11(2) and (3) and 17(2)(*b*) and (*c*) of the Directive.

(2) The HSE shall perform—

(*a*) the functions of the State under Articles 4, 6(2), 7(5) and (6), 10, 11(1), 15(3) and (4), 18(1) and (2) and 20 of the Directive, and

(*b*) the functions of the competent authority under Articles 17(2)(*a*), (*d*) and (*g*) and 21 of the Directive.

(3) The IMB and the HSE shall jointly perform—

(*a*) the functions of the State under Articles 11(4), 11(5), 16 and 22(1) of the Directive.

(*b*) the functions of the competent authority under Article 17(2)(*e*), (*f*) and (*h*) of the Directive.

(4) The IMB and the HSE may separately or jointly enter into a contractual arrangement with a person for the purposes of the person assisting them to perform their respective functions under these Regulations and the Directive.

(5) The IMB and the HSE may each delegate part or all of their respective tasks under these Regulations and the Directive.

(6) The IMB and the HSE shall issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted.

(7) The IMB may charge fees for its functions under the Directive and these Regulations in accordance with regulations made under section 13(1) of the Act, read in conjunction with section 4(1)(v) of the Act.

Part 2

Authorisation to carry out prescribed activities

Carrying out of prescribed activities

5. (1) A prescribed activity may only be carried out by, in or on behalf of a procurement organisation or transplantation centre acting in accordance with these Regulations and the Directive and an authorisation granted under Regulation 6 (including any conditions to which the authorisation is subject).

(2) Notwithstanding paragraph (1), a procurement organisation or a transplantation centre carrying out a prescribed activity on the coming into force of these Regulations may continue to carry out such prescribed activity provided that it submits an application for authorisation to the IMB no later than 6 weeks after the signing of these Regulations and only until the IMB has made a decision on that application.

Grant of authorisation

6. (1) The IMB may grant an authorisation to a procurement organisation or a transplantation centre to carry out any prescribed activity, having satisfied itself that such prescribed activity shall be carried out by persons complying with the requirements of these Regulations and the Directive.

(2) An application for an authorisation shall—

(*a*) be made in writing to the IMB,

(*b*) be signed by or on behalf of the procurement organisation or transplantation centre making the application, whether in ink or by means of an electronic signature,

(*c*) include all relevant information as determined by the IMB,

(*d*) include the name and qualifications of at least one responsible person designated under Regulation 11, and

(*e*) be accompanied by the appropriate fee.

(3) Where a procurement organisation or a transplantation centre applies, pursuant to paragraph (2), for an authorisation, the IMB may—

(*a*) grant the authorisation,

(*b*) refuse to grant the authorisation,

(*c*) grant the authorisation in respect of particular sites or prescribed activities only, or

(*d*) grant the authorisation subject to conditions.

(4) Where the IMB grants an authorisation, it shall give notice in writing to the procurement organisation or transplantation centre concerned specifying—

(*a*) the prescribed activities which the procurement organisation or transplantation centre may carry out in accordance with these Regulations and the Directive under the authorisation,

(*b*) the particular site(*s*) at which such activities may be carried out,

(*c*) where a prescribed activity is to be carried out by another person on behalf of the procurement organisation or transplantation centre, the names of all persons authorised to carry out such activity, and

(*d*) if the grant is subject to conditions, the conditions which apply to the carrying out of the prescribed activities.

(5) Where the IMB proposes to refuse to grant an authorisation, it shall serve a notice on the procurement organisation or transplantation centre concerned of the proposed refusal and the reasons for same, and shall, if any representations are made by or on behalf of the organisation or centre within 30 days after the date of such notice, consider the representations.

(6) Where the IMB, having considered the representations (if any) made by or on behalf of a procurement organisation or transplantation centre in response to a notice under paragraph (5), decides to refuse to grant an authorisation, it shall notify the organisation or centre stating the reasons on which its decision is based.

Removal, variation and addition of conditions

7. (1) Subject to the requirements of paragraph (2), the IMB may at any time remove or vary a condition attaching to an authorisation pursuant to Regulation 6(3)(*d*) or impose an additional condition to an authorisation.

(2) Where the IMB proposes to remove or vary a condition, or impose an additional condition, to an authorisation, pursuant to paragraph (1), it shall serve a notice on the procurement organisation or transplantation centre concerned which shall—

(*a*) give details of the condition which it proposes to remove, or of the variation which it proposes to make to an existing condition, or of the additional condition which it proposes to impose,

(*b*) give the reasons for its decision, and

(*c*) specify the date, which shall be not less than 14 days from the date on which the notice is served, from which the removal, variation or imposition shall apply.

Substantial change in prescribed activity

8. (1) A procurement organisation or transplantation centre shall not make a substantial change in a prescribed activity which it carries out without the prior written approval of the IMB.

(2) Any application by a procurement organisation or transplantation centre for approval to make a substantial change in a prescribed activity carried out by it shall be—

(*a*) made in writing to the IMB and signed by or on behalf of the procurement organisation or transplantation centre concerned, whether in ink or by means of an electronic signature, and

(*b*) accompanied by the appropriate fee.

(3) For the purpose of this Regulation, "a substantial change in a prescribed activity" means any change to the sites from which the procurement organisation or the transplantation centre concerned operates, or to the prescribed activities to be carried out by the organisation or centre, which would result in a failure to comply with the requirements of—

(*a*) these Regulations and the Directive, or

(*b*) the framework for quality and safety,

and which is likely to have a substantial impact on the conduct of, or might compromise the quality and safety of, the prescribed activity concerned.

Suspension or revocation of authorisation

9. (1) Subject to paragraph (2), the IMB may suspend or revoke an authorisation on one or more of the following grounds—

(*a*) that the procurement organisation or transplantation centre, or procurement or transplant process, concerned is not in compliance with the requirements of these Regulations and the Directive,

(*b*) that the donation, testing, characterisation, procurement, preservation, transport or transplantation of organs by the procurement organisation or transplantation centre concerned cannot be carried out safely,

(*c*) that the information given by the procurement organisation or transplantation centre concerned pursuant to Regulation 6(2)(*c*) or 31(3) was false or incomplete in any material respect,

(*d*) that the procurement organisation or transplantation centre concerned is not carrying out, or has indicated by a notice in writing that it no longer intends to carry out, the prescribed activities to which the authorisation relates, or

(*e*) the procurement organisation or transplantation centre does not have the staff, premises, equipment or facilities necessary for carrying out properly the prescribed activities to which the authorisation relates.

(2) Where the IMB proposes to suspend or revoke an authorisation, it shall serve a notice on the procurement organisation or transplantation centre concerned of the proposal and the reasons for same, and shall, if any representations are made by the organisation or centre within 30 days after the date of such notice, consider such representations.

(3) Where the IMB, having considered the representations (if any) made by or on behalf of a procurement organisation or transplantation centre in response to a notice under paragraph (2), decides to suspend or revoke an authorisation, it shall notify in writing the organisation or centre stating the reasons on which its decision is based.

(4) Where the IMB considers it necessary in the interests of safety, it may, by a notice served on the procurement organisation or transplantation centre concerned, suspend or revoke an authorisation—

(*a*) in a case where the IMB considers that it is necessary in the interests of safety, immediately, or

(*b*) in all other cases, from a date specified in the notice.

(5) A suspension of an authorisation pursuant to this Regulation shall be for such period as the IMB shall consider necessary having regard to the reasons for the suspension.

(6) A suspension or revocation of an authorisation under this Regulation may be total, or may be limited to a particular prescribed activity or to one or more prescribed activities carried out at a particular site or sites, or to a particular organ.

(7) Where, after a suspension has taken effect, the IMB considers that the authorisation should be further suspended or revoked, the IMB shall proceed in accordance with the provisions of this Regulation.

Compliance notice

10. (1) Where—

(*a*) a procurement organisation or transplantation centre has failed, in any material respect, to comply with the requirements of these Regulations, the Directive or the framework for quality and safety, or

(*b*) the information given by a procurement organisation or transplantation centre pursuant to Regulation 6(2)(*c*) or 31(3) was false or incomplete in any material respect,

and the IMB considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the authorisation of the procurement organisation or transplantation centre in the first instance, it may serve a notice on the responsible person of the procurement organisation or transplantation centre in accordance with paragraph (2).

(2) A notice served under this Regulation shall—

(*a*) identify the requirements of these Regulations and the Directive with which the procurement organisation or transplantation centre has failed to comply, or, in the case of false or incomplete information, the further information which is required,

(*b*) identify the action which the procurement organisation or transplantation centre is required to take, and

(*c*) give the timescale within which the procurement organisation or transplantation centre shall take the action identified in subparagraph (*b*).

(3) Where a procurement organisation or transplantation centre fails to comply with the requirements set out in a notice served under this Regulation within the specified timescale, the IMB may, by a further notice served on the procurement organisation or transplantation centre, suspend or revoke the authorisation concerned.

Responsible person

11. (1) A procurement organisation or transplantation centre shall designate at least one responsible person, qualified in accordance with paragraph (3), whose services shall be available to it.

(2) A responsible person designated under paragraph (1) shall ensure that—

(*a*) all authorised prescribed activities are carried out in accordance with the Directive and these Regulations,

(*b*) information is provided to the IMB as required under Regulations 6(2)(*c*) and 31(3),

(*c*) there is a documented system in place for ratifying that organs meet appropriate specifications for safety and quality for release, and for

ensuring that before any exception from the required standards of quality and safety shall occur, a documented risk-benefit analysis is performed which demonstrates that the expected benefits for the recipient outweigh the risks posed by such exception, and

(*d*) there is a reporting system in place to report with respect to serious adverse events and serious adverse reactions as required under Regulation 19.

(3) A procurement organisation or transplantation centre shall not designate a responsible person under paragraph (1) unless that person either—

(*a*) has a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of a university course of study, or another course of study recognised in Ireland as equivalent, or

(*b*) is otherwise considered by the IMB to be suitably qualified on the basis of academic qualifications and practical experience,

and has at least two years' practical experience which is directly relevant to the prescribed activity to be authorised.

(4) Procurement organisations and transplantation centres shall inform the IMB of the name and qualifications of any additional responsible person designated under paragraph (1) after the grant of the authorisation concerned.

(5) A responsible person may delegate any of the functions specified in paragraph (2) to other persons who shall be suitably qualified by training and experience to perform them.

(6) Procurement organisations and transplantation centres shall inform the IMB of the name of any person to whom functions have been delegated by the responsible person under paragraph (5), and the specific functions which have been delegated to such persons.

(7) Where a responsible person or a person to whom functions have been delegated under paragraph (5) is permanently or temporarily replaced, the procurement organisation or transplantation centre concerned shall without delay provide the IMB with the name of the replacement, details of his or her qualifications and the date on which the replacement began his or her duties.

(8) If the IMB considers that a responsible person does not meet the requirements of paragraph (3), it shall serve a notice to that effect on the procurement organisation or transplantation centre concerned.

(9) If, within 14 days of receiving a notice referred to in paragraph (8), a procurement organisation or transplantation centre is not able to demonstrate to the reasonable satisfaction of the IMB that the responsible person meets the requirements of paragraph (3), it shall, without delay—

(*a*) relieve him or her of the duties of responsible person in respect of the procurement organisation or transplantation centre,

(*b*) appoint a new responsible person in his or her place, and

(*c*) notify the IMB that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

Part 3

Quality and safety of organs

Framework for quality and safety

12. (1) The HSE, in consultation with the IMB, shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation or disposal, in compliance with the rules laid down in these Regulations and the Directive.

(2) The framework for quality and safety shall provide for, and include details of the roles and responsibilities regarding, the adoption and implementation of operating procedures for—

(*a*) the verification of donor identity,

(*b*) the verification of the details of the donor's or the donor's family's consent,

(*c*) the verification of the completion of the organ and donor characterisation in accordance with Regulation 15 and the Annex to the Directive,

(*d*) the procurement, preservation, packaging and labelling of organs in accordance with Regulations 13, 14 and 16,

(*e*) the transportation of organs in accordance with Regulation 16,

(*f*) ensuring traceability, in accordance with Regulation 18, while guaranteeing compliance with the European Union and national provisions on the protection of personal data and confidentiality,

(*g*) the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Regulation 19, and

(*h*) the management of serious adverse events and serious adverse reactions in accordance with Regulation 19.

(3) In respect of the operating procedures referred to in paragraph (2)(*f*), (*g*) and (*h*), the framework for quality and safety shall include the responsibilities of procurement organisations, transplantation centres and European organ exchange organisations, as appropriate.

(4) The framework for quality and safety shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.

(5) In carrying out prescribed activities, procurement organisations and transplantation centres shall comply with the framework for quality and safety.

Procurement organisations

13. (1) The IMB shall indicate in an authorisation granted to a procurement organisation the prescribed activities that the organisation concerned may undertake.

(2) The IMB shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of procurement organisations.

Organ procurement

14. (1) Procurement organisations shall ensure that—

(*a*) medical activities, such as donor selection and evaluation, are performed under the advice and guidance of a doctor of medicine as referred to in Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005[4], and

(*b*) procurement material and equipment are managed in accordance with relevant European Union, international and national legislation, standards and guidelines on the sterilisation of medical devices.

(2) The HSE and procurement organisations shall ensure that procurement takes place in operating theatres, which are designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured.

Organ and donor characterisation

15. (1) Procurement organisations shall ensure that all procured organs and donors thereof are characterised before transplantation through the collection of—

(*a*) the set of minimum data set out in Part A of the Annex to the Directive, and

(*b*) the set of complementary data set out in Part B of the Annex to the Directive, based on the decision of the procurement organisation concerned, taking into account the availability of such information and the particular circumstances of the case

(2) Notwithstanding paragraph (1), if according to a risk-benefit analysis in a particular case, including in life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be

[4]OJ L 255, 30.9.2005, p.22

considered for transplantation where not all of the minimum data specified in Part A of the Annex to the Directive are available.

(3) In order to meet the quality and safety requirements laid down in these Regulations and the Directive, procurement organisations shall—

(*a*) in the case of living donation, endeavour to obtain all necessary information from the donor and provide him or her with the information he or she needs to understand the consequences of donation, or

(*b*) in the case of deceased donation, where possible and appropriate, endeavour to obtain all necessary information from relatives of the deceased donor or other persons.

and, in either case, it shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of that information.

(4) The HSE and procurement organisations shall ensure that the tests required for organ and donor characterisation shall be carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.

(5) The HSE and procurement organisations shall ensure that organisations, bodies and laboratories involved in organ and donor characterisation have appropriate operating procedures in place to ensure that the information on organ and donor characterisation reaches the transplantation centre in due time.

(6) Where organs are exchanged between the State and another Member State, the HSE shall ensure that the information on organ and donor characterisation, as specified in the Annex to the Directive, is transmitted to the procurement organisation or transplantation centre in the other Member State with which the organ is exchanged, in conformity with the procedures established by the Commission pursuant to Article 29 of the Directive.

Transport of organs

16. (1) Subject to paragraph (2), procurement organisations and transplantation centres shall ensure that the following requirements are met—

(*a*) the organisations, bodies or companies involved in the transportation of organs have appropriate operating procedures in place to ensure the integrity of the organs during transport and a suitable transport time,

(*b*) the shipping containers used for transporting organs are labelled with the following information:

(i) identification of the procurement organisation and the establishment where the procurement took place, including their addresses and telephone numbers,

(ii) identification of the transplantation centre of destination, including its address and telephone number,

(iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked "HANDLE WITH CARE", and

(iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position, and

(*c*) the organs transported are accompanied by a report on the organ and donor characterisation.

(2) The requirements laid down in paragraph (1)(*b*) need not be met where the transportation is carried out within the same establishment.

Transplantation centres

17. (1) The IMB shall indicate in an authorisation granted to a transplantation centre the prescribed activities that the centre concerned may undertake.

(2) A transplantation centre shall verify before proceeding to transplantation that—

(*a*) the organ and donor characterisation are completed and recorded in accordance with Regulation 15 and the Annex to the Directive, and

(*b*) the conditions of preservation and transport of shipped organs have been maintained.

(3) The IMB shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of transplantation centres.

Traceability

18. (1) The HSE shall, in conjunction with procurement organisations and transplantation centres, ensure that all organs procured, allocated and transplanted in the State can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients.

(2) The HSE shall, in conjunction with procurement organisations and transplantation centres, ensure the implementation of a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it.

(3) The HSE, procurement organisations and transplantation centres shall ensure that, with regard to the system referred to in paragraph (2), confidentiality and data security measures are in place in compliance with European Union and national provisions, as referred to in Regulation 24.

(4) The HSE, procurement organisations and transplantation centres shall keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal and the information on organ and donor characterisation as specified in the Annex to the Directive, in accordance with the framework for quality and safety, for a minimum of 30 years after donation.

(5) The data referred to in paragraph (4) may be stored in electronic form.

(6) Where organs are exchanged between the State and another Member State, the HSE shall transmit the necessary information to ensure the traceability of organs in conformity with the procedures established by the Commission pursuant to Article 29 of the Directive.

Reporting system and management concerning serious adverse events and reactions

19. (1) The HSE shall, in conjunction with procurement organisations and transplantation centres, ensure that there is an appropriate system in place to collect, collate, report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

(2) A procurement organisation or transplantation centre carrying out a prescribed activity shall—

(*a*) through its responsible person, ensure that operating procedures are in place to ensure compliance with the system established pursuant to paragraph (1),

(*b*) through its responsible person, ensure that operating procedures are in place for the management of serious adverse events and serious adverse reactions as provided for in the framework for quality and safety, and

(*c*) transmit relevant and necessary information simultaneously to the IMB and to the HSE,

(3) Notwithstanding paragraph (2)(*b*) and (*c*), the responsible person in a procurement organisation or transplantation centre carrying out a prescribed activity shall ensure that operating procedures are in place for the notification, in due time, of—

(*a*) any serious adverse event and any serious adverse reaction, to the IMB and the procurement organisation or transplantation centre concerned, and

(*b*) the management measures with regard to serious adverse events and serious adverse reactions, to the IMB.

(4) Where organs are exchanged between the State and another Member State, the procurement organisation or transplantation centre concerned shall ensure that serious adverse events and serious adverse reactions are reported to the IMB and to the HSE, and the IMB and the HSE shall share such reports with the competent authority concerned in any other Member State concerned in conformity with the procedures established by the Commission pursuant to Article 29 of the Directive.

(5) The IMB and the HSE shall ensure the interconnection between the reporting system referred to in paragraph (1) and the notification system established in accordance with Article 11(1) of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004[5] and Regulation 10(3) of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006).

Healthcare personnel

20. Procurement organisations and transplantation centres shall ensure that healthcare personnel directly involved in the chain from donation to the transplantation or disposal of organs are suitably qualified or trained and competent to perform their tasks and are provided with the relevant training, as specified in the framework for quality and safety pursuant to Regulation 12(4).

Part 4

Donor and recipient protection and donor selection and evaluation

Principles governing organ donation

21. (1) Subject to paragraph (2), donation from deceased and living donors shall be voluntary and unpaid.

(2) Living donors may receive compensation for donation, provided it is strictly limited to making good the expenses and loss of income related to the donation. The Minister shall define the conditions under which such compensation may be granted, while avoiding there being any financial incentives or benefit for a potential donor.

(3) Advertising the need for, or availability of, organs, where such advertising is with a view to offering or seeking financial gain or comparable advantage, is prohibited.

(4) Procurement shall be carried out on a non-profit basis.

Consent requirements

22. (1) Organs shall not be procured in the case of a living donor unless the donor has given informed consent to the donation or the donation is otherwise permitted by law.

(2) Organs shall not be procured in the case of a deceased donor unless consent to the donation has been given by the deceased donor's next of kin.

[5]OJ No. L 136, 30.4.2004, p. 85.

Quality and safety aspects of living donation

23. (1) Procurement organisations shall—

(*a*) take all necessary measures to ensure the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation and

(*b*) ensure that living donors are selected on the basis of their health and medical history, by suitably qualified or trained and competent professionals.

(2) Selection assessments carried out pursuant to paragraph (1)(*b*) may provide for the exclusion of persons whose donation could present unacceptable health risks.

(3) The HSE and transplantation centres shall—

(*a*) ensure that a register or record of the living donors is kept, in accordance with European Union and national provisions on the protection of the personal data and statistical confidentiality,

(*b*) endeavour to carry out the follow-up of living donors, and

(*c*) implement and maintain a system in order to comply with Regulation 19 and to identify, report and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.

Protection of personal data, confidentiality and security of processing

24. (1) The IMB, the HSE, procurement organisations and transplantation centres shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in conformity with European Union provisions on the protection of personal data, such as Articles 8(3), 16, 17 and 28(2) of the Data Protection Directive, and shall take all necessary measures to ensure that—

(*a*) the data processed are kept confidential and secure in accordance with Articles 16 and 17 of the Data Protection Directive,

(*b*) donors and recipients whose data are processed within the scope of these Regulations and the Directive are not identifiable, except as permitted by Article 8(2) and (3) of the Data Protection Directive, and the Data Protection Acts 1988 and 2003, and

(*c*) the principles relating to data quality, as set out in Article 6 of the Data Protection Directive, are met.

(2) The IMB, the HSE, procurement organisations and transplantation centres shall ensure that all information, including genetic information which is

collected for the purposes of these Regulations and the Directive, is held securely so that it is—

(*a*) available for the purpose of tracing donations,

(*b*) not disclosed except—

(i) in accordance with one or more of the requirements of paragraph (3), or

(ii) where it has been rendered anonymous so that donors are no longer identifiable, and

(*c*) subject to safeguards against unauthorised additions, deletions or modifications to donor files or deferral records.

(3) The requirements of this paragraph are as follows:

(*a*) the disclosure is made in accordance with an order of a court or is otherwise required by law,

(*b*) the disclosure is to an authorised officer, or

(*c*) the disclosure is for the purpose of tracing a donation from donor to recipient or recipient to donor.

(4) Where a disclosure is made to an authorised officer pursuant to paragraph (3)(*b*), the authorised officer shall not further disclose the information received unless—

(*a*) the disclosure is made in accordance with an order of a court or is otherwise required by law,

(*b*) the disclosure is to another authorised officer or an officer of the IMB where this is necessary for the proper performance of any function of any such officer, or

(*c*) the information has been rendered anonymous so that the donors are no longer identifiable.

(5) Where a disclosure is made pursuant to paragraph (3), the person to whom the disclosure is made shall not further disclose the information he or she receives other than in accordance with the requirements of that paragraph.

(6) The IMB, the HSE, procurement organisations and transplantation centres shall put in place procedures to ensure that any discrepancies relating to data which are brought to their attention are resolved without delay.

(7) The IMB, the HSE, procurement organisations and transplantation centres shall ensure that the identity of a recipient is not disclosed to the donor or his or her family, or vice versa, without prejudice to legislation which may come into force on the conditions for disclosure.

Part 5

Recording and reporting of activities under regulations

Reporting obligations of HSE

25. (1) The HSE shall—

(*a*) keep a record of the activities of procurement organisations and transplantation centres, including aggregated numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in accordance with European Union and national provisions on the protection of personal data and statistical confidentiality,

(*b*) draw up and make publicly accessible an annual report on activities referred to in subparagraph (*a*), and

(*c*) establish and maintain an updated record of procurement organisations and transplantation centres.

(2) The HSE shall, upon the request of the Commission or another Member State, provide information on the record of procurement organisations and transplantation centres.

Reporting obligations of IMB

26. (1) The IMB shall keep such records of information which it receives from, or relating to, procurement organisations or transplantation centres as it considers appropriate in accordance with these Regulations and the Directive and shall, in particular, keep records relating to—

(*a*) authorisations under Regulation 6,

(*b*) notifications of serious adverse events and serious adverse reactions by procurement organisations and transplantation centres pursuant to Regulation 19, and

(*c*) inspections or requests for information under Regulation 31.

(2) The IMB shall maintain a publicly accessible register of procurement organisations and transplantation centres, specifying the prescribed activities for which they have been authorised.

Reporting to Commission

27. The IMB and the HSE shall report to the Commission before 27 August 2013 and every three years thereafter on the activities undertaken in relation to the provisions of the Directive, and on the experience gained in implementing it.

Part 6

Organ exchange with third countries and European organ exchange organisations

Organ exchange with third countries

28. (1) The HSE shall supervise organ exchange with third countries and may, for this purpose, conclude agreements with counterparts in third countries.

(2) The supervision of organ exchange with third countries may be delegated by the HSE to European organ exchange organisations.

(3) Organ exchange, as referred to in paragraph (1), shall be allowed only where the organs—

(*a*) can be traced from the donor to the recipient and vice versa, and

(*b*) meet quality and safety requirements equivalent to those laid down in these Regulations and the Directive.

European organ exchange organisations

29. The HSE may conclude agreements with European organ exchange organisations, provided that it is satisfied that such organisations comply with the requirements laid down in these Regulations and the Directive, delegating functions to those organisations, including—

(*a*) the performance of activities provided for under the framework for quality and safety, and

(*b*) specific tasks in relation to the exchange of organs between the State and third countries.

Part 7

Enforcement, offences and penalties

Interpretation of Part 7

30. In this Part—

"inspect" includes search;

"premises" means any place, ship or other vessel, aircraft, railway wagon or other vehicle, and includes a container used to transport relevant things;

"record" includes, in addition to a record in writing—

(*a*) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in legible or audible form,

(*b*) a film, tape or other device in which visual images are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in visual form, and

(*c*) a photograph,

and any reference to a copy of a record includes—

(*d*) in the case of a record to which paragraph (*a*) of this definition applies, a transcript of the sounds or signals embodied therein,

(*e*) in the case of a record to which paragraph (*b*) of this definition applies, a still reproduction of the images embodied therein, and

(*f*) in the case of a record to which paragraphs (*a*) and (*b*) of this definition apply, such a transcript together with such a still reproduction;

"relevant thing" means—

(*a*) an organ, or

(*b*) any article or substance used in the donation, testing, characterisation, procurement, preservation, transport and transplantation of human organs.

Inspections and requests for information

31. (1) The IMB shall conduct a regular inspection of the premises of a procurement organisation or transplantation centre, including any third party facilities used by the organisation or centre, not less than once every 2 years, for the purpose of ensuring that—

(*a*) the procedures and activities carried out by the procurement organisation or transplantation centre and the facilities of any such third party comply with the requirements of the Directive and these Regulations,

(*b*) documents or other records relating to the requirements of the Directive and these Regulations are examined, and

(*c*) problems relating to compliance with those requirements are identified.

(2) The IMB may conduct such additional inspections of the premises of procurement organisations and transplantation centres and the facilities of any third party as it considers necessary for the purpose of ensuring compliance with the requirements of the Directive and these Regulations.

(3) The IMB may serve a notice on a procurement organisation or transplantation centre, or any third party providing facilities to same, requiring that it furnish the IMB with such information concerning its compliance with the

Directive and these Regulations and within such period as shall be specified in the notice.

(4) Any procurement organisation, transplantation centre or third party which receives a request for information in accordance with paragraph (3) shall provide the information requested within the period specified in the notice.

(5) In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, the IMB shall request such information, conduct such inspections, or carry out control measures, in accordance with the Directive and these Regulations, as it shall consider appropriate.

(6) Any reference to an inspection of a site which the IMB is required or empowered to conduct by virtue of this Regulation, shall be construed so as to include an inspection of premises within the State at which any of the prescribed activities are carried out by any person on behalf of, and pursuant to a contractual arrangement with, a procurement organisation or transplantation centre.

(7) For the avoidance of doubt, it is hereby declared that the IMB's functions under this Regulation in relation to a procurement organisation or transplantation centre are also applicable in the case of a procurement organisation or transplantation centre seeking authorisation under Regulation 6.

(8) The IMB, on receipt of a duly justified request from the competent authority in another Member State, shall organise such inspection or other control measures as are reasonably required.

(9) The IMB shall, upon the request of another Member State or the Commission, provide information on the results of inspections and control measures carried out under the Directive and these Regulations.

Authorised officers

32. (1) The IMB—

(*a*) may appoint such and so many persons as the IMB thinks fit to be authorised officers for the purposes of these Regulations, and

(*b*) shall furnish each authorised officer appointed by it with a warrant of the authorised officer's appointment.

(2) An authorised officer (other than an authorised officer who is an officer of Customs and Excise) shall, when performing a function imposed under these Regulations on an authorised officer, produce his or her warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of enforcing compliance with these Regulations, including conducting inspections pursuant to Regulation 31, an authorised officer may—

(*a*) subject to paragraph (5), enter (if necessary by the use of reasonable force), at all reasonable times, any premises which he or she has reasonable grounds to believe that it is necessary to visit, including—

(i) any premises owned or managed by a procurement organisation or a transplantation centre, or at which the procurement organisation or transplantation centre carries out any prescribed activities, or any premises that is connected to the management, procurement, transplantation or any supply, storage, import or export of the relevant thing,

(ii) any premises of any person who carries out any prescribed activity on behalf of, and pursuant to a contractual arrangement, with a procurement organisation or transplantation centre,

(iii) where any facilities for donor evaluation and testing are in the premises of any person or body other than a procurement organisation or transplantation centre, those facilities in that person's premises, and

(iv) any premises at which books, records or other documents (including financial documents and documents stored in non-legible form) relating to any prescribed activity are stored or kept,

(*b*) at such premises inspect, and take copies of, any books, records, other documents (including documents stored in non-legible form) or extracts therefrom, which he or she finds in the course of his or her inspection,

(*c*) remove any such books, records or other documents from such premises and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(*d*) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of—

(i) the premises,

(ii) any relevant thing at the premises, or

(iii) any equipment, machinery or plant at the premises,

as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(*e*) require any person at the premises or the owner or person in charge of the premises, and any person employed there, to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as

he or she may reasonably require for the purposes of his or her functions under these Regulations,

(*f*) without payment, take samples of any relevant thing found at the premises for the purposes of any test, examination or analysis,

(*g*) direct that such relevant thing found at the premises as he or she, upon reasonable grounds, believes does not comply with the requirements of these Regulations not be sold or distributed or moved from the premises, without his or her consent,

(*h*) secure for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under these Regulations,

(*i*) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations,

(*j*) without payment, take samples of any relevant thing, detained pursuant to subparagraph (i), for the purposes of any test, examination, or analysis, or

(*k*) where the taking of samples of any relevant thing pursuant to subparagraph (*f*) or (*j*) is, for whatever reason, not practicable, without payment take the relevant thing concerned for the purposes of any test, examination or analysis.

(4) When performing a function under these Regulations, an authorised officer may, subject to any warrant issued under paragraph (6), be accompanied by such number of—

(*a*) other authorised officers,

(*b*) members of the Garda Síochána, or

(*c*) persons with expertise relating to any relevant thing,

as he or she considers appropriate in the circumstances of the case.

(5) An authorised officer shall not enter a dwelling, other than—

(*a*) with the consent of the occupier, or

(*b*) in accordance with a warrant issued under paragraph (6).

(6) Upon the application of an authorised officer, a judge of the District Court, if satisfied that there are reasonable grounds for believing that—

(*a*) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling,

(*b*) books, records or other documents (including documents stored in non-legible form) referred to in paragraph (3)(*a*)(iv) are being stored or kept in any dwelling, or

(*c*) a dwelling is occupied in whole or in part by an undertaking carrying out any prescribed activity,

may issue a warrant authorising a named authorised officer, accompanied by such other authorised officers, members of the Garda Síochána, or persons with expertise relating to any relevant thing as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under paragraph (3)(*b*) to (*k*).

(7) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under these Regulations, he or she may require that person to provide him or her with his or her name and the address at which he or she ordinarily resides.

(8) A statement or admission made by a person pursuant to a requirement under paragraph (3)(*e*) shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under Regulation 35(2)(*g*)).

(9) Nothing in this Regulation shall be taken to compel the production by any person of a document which he or she would be exempt from producing in proceedings in a court on the ground of legal professional privilege.

Taking of samples, etc. by authorised officers

33. (1) Subject to paragraph (3), where an authorised officer takes a sample of a relevant thing, he or she shall—

(*a*) divide the sample into 3 approximately equal parts,

(*b*) place each part into separate containers, and

(*c*) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by that authorised officer.

(2) Where an authorised officer has complied with paragraph (1), he or she shall—

(*a*) offer one of the sealed containers to the owner or person for the time being in charge or possession of the relevant thing from which the sample concerned was taken,

(*b*) retain one of the sealed containers, and

(c) forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by a person mentioned in Regulation 34(1)(a),(b) or (c).

(3) Where a relevant thing is contained in a container and its division into parts pursuant to paragraph (1) is, for whatever reason, not practicable, an authorised officer, who wishes to take samples of the relevant thing for the purposes of any test, examination or analysis, shall take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of paragraph (1), and the provisions of paragraphs (1) and (2) shall apply thereto accordingly.

(4) Where an authorised officer takes a relevant thing pursuant to Regulation 32(3)(*k*), he or she shall—

(*a*) place the relevant thing in a container,

(*b*) forthwith seal and mark the container in such a manner as to identify it as a relevant thing taken pursuant to that section, and

(*c*) forward, or cause to be forwarded, the sealed container for test, examination or analysis of the relevant thing by a person mentioned in Regulation 34(1)(*a*), (*b*) or (*c*).

Certificate of result of test, etc. of sample, etc

34. (1) In any proceedings for an offence under these Regulations, a certificate in the form specified in the Schedule to these Regulations signed by—

(*a*) either—

(i) the State Chemist, or

(ii) another chemist employed or engaged at the State Laboratory and authorised by the State Chemist to sign the certificate,

(*b*) either—

(i) a public analyst appointed under section 10 of the Sale of Food and Drugs Acts 1875 to 1936, or

(ii) another analyst authorised by such a public analyst to sign the certificate, or

(*c*) a chemist or analyst appointed by the IMB,

stating the result of any test, examination or analysis of a sample of any relevant thing, or of a relevant thing, as the case may be, forwarded under Regulation 33(2)(*c*) or (4)(*c*) shall, with regard to that sample of the relevant thing, or the relevant thing, as the case may be, be evidence of the matters stated in the certificate unless the contrary is proved.

(2) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that purports to bear the name of the manufacturer or importer of that thing, or of the person who placed that thing on the market, shall, unless the contrary is proved, be evidence that the relevant thing was manufactured or imported, or placed on the market, as the case may be, by the person so named.

(3) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that bears a trademark shall, unless the contrary is proved, be evidence that the thing was manufactured by the person who at the time of the alleged commission of the offence owned that trademark.

(4) In this Regulation "trademark" has the same meaning as it has in the Trade Marks Act 1996 (No. 6 of 1996).

Offences

35. (1) A person who contravenes Regulation 5(1), 8(1), 11(1), 14(1), 15(4) or (5), 16(1)(*b*), 17(2), 18, 19(2) or (3), 20, 21(1), (2) or (4), 22, 23(1)(*b*) or 24 is guilty of an offence.

(2) A person—

(*a*) who fails to comply with a notice of suspension or revocation of an authorisation, served pursuant to Regulation 9, except where the operation of that notice has been suspended or has been withdrawn or revoked by the IMB,

(*b*) knowingly supplies an organ which is not labelled in accordance with the requirements of Regulation 16(1)(*b*),

(*c*) discloses any information referred to in Regulation 24(2) to which he or she has access by virtue of these Regulations, otherwise than in accordance with the provision of Regulation 24(3) and (4),

(*d*) obstructs or interferes with an authorised officer, a member of the Garda Síochána or a person with expertise relating to any relevant thing, in the course of performing a function conferred on him or her by these Regulations or a warrant under Regulation 32(6),

(*e*) impedes the performance by the officer, member, or person with expertise, as the case may be, referred to in subparagraph (*d*), of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the officer, member, or person with expertise, as the case may be, pursuant to Regulation 32,

(*f*) in purported compliance with a request or requirement referred to in subparagraph (*e*), or in answer to a question referred to in subparagraph (*e*), gives information to the officer, member, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect,

(*g*) falsely represents himself or herself to be an authorised officer,

(*h*) imports into the State an organ from a country or territory outside the European Union which does not meet standards of quality and safety equivalent to those laid down pursuant to Regulation 12,

(*i*) procures or sells, including brokering the procurement or sale, for exchange of money or value an organ contrary to these Regulations and the Directive, or

(*j*) trafficks, harbours, imports or exports an organ contrary to these Regulations and the Directive,

(*k*) who fails to comply with the directions of an authorised officer pursuant to Regulation 32(3)(*g*),

is guilty of an offence.

(3) Where a body corporate, or a person acting on behalf of a body corporate, commits an offence under these Regulations and the offence is committed with the consent, connivance or approval of, or is attributable to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(4) Where the affairs of a body corporate are managed by its members, paragraph (3) applies as if the reference to a director in that subsection were a reference to a member of the body corporate.

Penalties

36. (1) A person guilty of an offence under these Regulations is liable—

(*a*) on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both, or

(*b*) on conviction on indictment—

(i) in the case of a first offence, to a fine not exceeding €120,000 or imprisonment for a term not exceeding 3 years or both, and

(ii) in the case of any subsequent offence, to a fine not exceeding €300,000 or imprisonment for a term not exceeding 3 years or both.

(2) On conviction for an offence under these Regulations, the court may, in addition to any other penalty—

(*a*) order any relevant thing to which the offence relates to be forfeited to the IMB for destruction or disposal as the IMB thinks fit, and

(*b*) upon application made to it by or on behalf of the IMB, order the person convicted of the offence to pay to the relevant person all or part of the costs of the test, examination or analysis of such relevant thing, or its such destruction or disposal subject to such conditions, if any, as are specified in the order.

(3) In any proceedings for an offence under these Regulations, where no conviction is recorded, the court may, upon application made to it by or on behalf of the IMB, order any relevant thing to which the offence relates to be forfeited to the IMB for destruction or disposal.

Defence of due diligence

37. (1) In any proceedings for an offence under these Regulations, it shall be a defence for the person charged to prove that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to a defence under paragraph (1), the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond all reasonable doubt that it is not.

Summary proceedings may be brought by IMB

38. Summary proceedings for an offence under these Regulations may be brought and prosecuted by the IMB.

Regulation 34

Schedule

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012

Certificate stating results of test, examination or analysis

This certificate is issued by me, the undersigned, for the purpose of Regulation 34 of the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012, being—

[1] _____ .

I hereby certify that I received, on the ____ day of _____, from

[2] _____ of _____a sample of the relevant thing/the relevant thing*, being [3] _____ for test, examination or analysis; which was undamaged, duly sealed and marked [4] _____.

I further certify that the said sample/relevant thing* has been tested, examined or analysed by me or under my direction and that the results are as follows—

[5]

Signature _____

Date _____

Address _____

_____

_____

1. Here insert official title of person signing the certificate.

2. Here insert the name of the authorised officer who submitted the sample of the relevant thing, or the relevant thing, as the case may be.

3. Here insert the name or description of the relevant thing.

4. Here insert distinguishing mark on the sample of the relevant thing, or the relevant thing, as the case may be, and the date shown on its container as the date of sampling, or the date on which the relevant thing was taken into possession, as the case may be.

5. Here insert the relevant results as appropriate.

* Delete whichever is inapplicable

L.S.

GIVEN under my Official Seal,
27 August 2012.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations give effect to Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

These Regulations may be cited as the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,
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(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)
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Human Tissue Act 2004

CHAPTER 30

CONTENTS

Human Tissue Act 2004

2004 CHAPTER 30

An Act to make provision with respect to activities involving human tissue; to make provision about the transfer of human remains from certain museum collections; and for connected purposes. [15th November 2004]

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

PART 1

REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

1 Authorisation of activities for scheduled purposes

(1) The following activities shall be 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 relevant material 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 relevant material which has come from a human body;

(e) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material 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 relevant material which has come from a human body;

(g) the use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a deceased person.

(2) The storage of the body of a deceased person for use for the purpose of anatomical examination shall be lawful if done—

(a) with appropriate consent, and

(b) after the signing of a certificate—

(i) under section 22(1) of the Births and Deaths Registration Act 1953 (c. 20), or

(ii) under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)),

of the cause of death of the person.

(3) The use of the body of a deceased person for the purpose of anatomical examination shall be lawful if done—

(a) with appropriate consent, and

(b) after the death of the person has been registered—

(i) under section 15 of the Births and Deaths Registration Act 1953, or

(ii) under Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.

(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) relevant material to which subsection (6) applies.

(5) This subsection applies to a body if—

(a) it has been imported, or

(b) it is the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.

(6) This subsection applies to relevant material if—

(a) it has been imported,

(b) it has come from a body which has been imported, or

(c) it is material which has come from the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.

(7) Subsection (1)(d) does not apply to the storage of relevant material for use for the purpose of research in connection with disorders, or the functioning, of the human body if—

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

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

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

(a) the material 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 in accordance with regulations made by the Secretary of State, 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 material has come can be identified.

(10) The following activities shall be lawful—

(a) the storage for use for a purpose specified in Part 2 of Schedule 1 of any relevant material which has come from the body of a living person;

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

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

(11) The Secretary of State 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.

(12) Nothing in this section applies to—

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

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

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

2 "Appropriate consent": children

(1) This section makes provision for the interpretation of "appropriate consent" in section 1 in relation to an activity involving the body, or material from the body, of a person who is a child or has died a child ("the child concerned").

(2) Subject to subsection (3), where the child concerned is alive, "appropriate consent" means his consent.

(3) Where—

(a) the child concerned is alive,

(b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, and

(c) either he is not competent to deal with the issue of consent in relation to the activity or, though he is competent to deal with that issue, he fails to do so,

"appropriate consent" means the consent of a person who has parental responsibility for him.

(4) Where the child concerned has died and the activity is one to which subsection (5) applies, "appropriate consent" means his 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 only valid 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 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 his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;

(b) if paragraph (a) does not apply—

(i) the consent of a person who had parental responsibility for him immediately before he died, or

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

3 "Appropriate consent": adults

(1) This section makes provision for the interpretation of "appropriate consent" in section 1 in relation to an activity involving the body, or material 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 his consent.

(3) Where the person concerned has died and the activity is one to which subsection (4) applies, "appropriate consent" means his 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 only valid 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 his 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—

(i) section 9 of the Wills Act 1837 (c. 26), or

(ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).

(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 his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;

(b) if—

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

(ii) he has appointed a person or persons under section 4 to deal after his 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, the consent of a person who stood in a qualifying relationship to him immediately before he died.

(7) Where the person concerned has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity, the appointment shall be disregarded for the purposes of subsection (6) if no one is able to give consent under it.

(8) If it is not reasonably practicable to communicate with a person appointed under section 4 within the time available if consent in relation to the activity is to be acted on, he shall be treated for the purposes of subsection (7) as not able to give consent under the appointment in relation to it.

4 Nominated representatives

(1) An adult may appoint one or more persons to represent him after his death in relation to consent for the purposes of section 1.

(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 only valid if—

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

(b) it is signed at the direction of the person making it, in his 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—

(i) section 9 of the Wills Act 1837 (c. 26), or

(ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).

(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 appointment.

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

(a) he is not an adult, or

(b) he is of a description prescribed for the purposes of this provision by regulations made by the Secretary of State.

5 Prohibition of activities without consent etc.

(1) A person commits an offence if, without appropriate consent, he does an activity to which subsection (1), (2) or (3) of section 1 applies, unless he reasonably believes—

(a) that he does the activity with appropriate consent, or

(b) that what he does is not an activity to which the subsection applies.

(2) A person commits an offence if—

(a) he falsely represents to a person whom he knows or believes is going to, or may, do an activity to which subsection (1), (2) or (3) of section 1 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) he knows that the representation is false or does not believe it to be true.

(3) Subject to subsection (4), a person commits an offence if, when he does an activity to which section 1(2) applies, neither of the following has been signed in relation to the cause of death of the person concerned—

(a) a certificate under section 22(1) of the Births and Deaths Registration Act 1953 (c. 20), and

(b) a certificate under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)).

(4) Subsection (3) does not apply—

(a) where the person reasonably believes—

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

(ii) that what he does is not an activity to which section 1(2) applies, or

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

(5) Subject to subsection (6), a person commits an offence if, when he does an activity to which section 1(3) applies, the death of the person concerned has not been registered under either of the following provisions—

(a) section 15 of the Births and Deaths Registration Act 1953, and

(b) Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.

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

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

(b) that what he does is not an activity to which section 1(3) applies.

(7) A person guilty of an offence under this section shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum;

(b) on conviction on indictment—

(i) to imprisonment for a term not exceeding 3 years, or

(ii) to a fine, or

(iii) to both.

(8) In this section, "appropriate consent" has the same meaning as in section 1.

6 Activities involving material from adults who lack capacity to consent

Where—

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

(i) is an adult, and

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

(b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force,

there shall for the purposes of this Part be deemed to be consent of his to the activity if it is done in circumstances of a kind specified by regulations made by the Secretary of State.

7 Powers to dispense with need for consent

(1) If the Authority is satisfied—

(a) that relevant 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 the material 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 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 subsection (3) apply to the material for the benefit of the other person.

(2) If the Authority is satisfied—

(a) that relevant 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 the material be used 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 subsection,

it may direct that subsection (3) apply to the material for the benefit of the other person.

(3) Where material is the subject of a direction under subsection (1) or (2), there shall for the purposes of this Part be deemed to be consent of the donor to the use of the material for the purpose of obtaining scientific or medical information about him which may be relevant to the person for whose benefit the direction is given.

(4) The Secretary of State may by regulations enable the High Court, in such circumstances as the regulations may provide, to make an order deeming there for the purposes of this Part to be appropriate consent 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 relevant material of which the body consists or which it contains,

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

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

8 Restriction of activities in relation to donated material

(1) Subject to subsection (2), a person commits an offence if he—

(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.

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

(3) A person guilty of an offence under this section shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum;

(b) on conviction on indictment—

(i) to imprisonment for a term not exceeding 3 years, or

(ii) to a fine, or

(iii) to both.

(4) 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 disposal, or

(d) a purpose specified in regulations made by the Secretary of State.

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

(a) the body of a deceased person, or

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

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

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

9 Existing holdings

(1) In its application to the following activities, section 1(1) shall have effect with the omission of the words "if done with appropriate consent"—

(a) the storage of an existing holding for use for a purpose specified in Schedule 1;

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

(2) Subsection (1) does not apply where the existing holding is a body, or separated part of a body, in relation to which section 10(3) or (5) has effect.

(3) Section 5(1) and (2) shall have effect as if the activities mentioned in subsection (1) were not activities to which section 1(1) applies.

(4) In this section, "existing holding" means—

(a) the body of a deceased person, or

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

held, immediately before the day on which section 1(1) comes into force, for use for a purpose specified in Schedule 1.

10 Existing anatomical specimens

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

(2) Subsection (3) applies where—

(a) before section 1 comes into force, authority is given under section 4(2) or (3) of the Anatomy Act 1984 (c. 14) for the person's body to be used for anatomical examination, and

(b) section 1 comes into force before anatomical examination of the person's body is concluded.

(3) During so much of the relevant period as falls after section 1 comes into force, that authority shall be treated for the purposes of section 1 as appropriate consent in relation to—

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

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

(4) Subsection (5) applies where—

(a) before section 1 comes into force, authority is given under section 6(2) or (3) of the Anatomy Act 1984 for possession of parts (or any specified parts) of the person's body to be held after anatomical examination of his body is concluded, and

(b) anatomical examination of the person's body is concluded—

(i) after section 1 comes into force, but

(ii) before the end of the period of three years beginning with the date of the person's death.

(5) With effect from the conclusion of the anatomical examination of the person's body, that authority shall be treated for the purposes of section 1 as appropriate consent in relation to—

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

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

(ii) is such that the person cannot be recognised simply by examination of the part, and

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

(6) Where for the purposes of section 1 there would not be appropriate consent in relation to an activity but for authority given under the Anatomy Act 1984 (c. 14) being treated for those purposes as appropriate consent in relation to the activity, section 1(1) to (3) do not authorise the doing of the activity otherwise than in accordance with that authority.

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

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

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

(8) In subsection (5), "qualifying purpose" means a purpose specified in paragraph 6 or 9 of Schedule 1.

(9) The Secretary of State may by order amend subsection (8).

11 Coroners

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

(2) Where a person knows, or has reason to believe, that—

(a) the body of a deceased person, or

(b) relevant material which has come from the body of a deceased person,

is, or may be, required for purposes of functions of a coroner, he shall not act on authority under section 1 in relation to the body, or material, except with the consent of the coroner.

12 Interpretation of Part 1

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.

PART 2

REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE

The Human Tissue Authority

13 The Human Tissue Authority

(1) There shall be a body corporate to be known as the Human Tissue Authority (referred to in this Act as "the Authority").

(2) Schedule 2 (which makes further provision about the Authority) has effect.

14 Remit

(1) The following are the activities within the remit of the Authority—

(a) the removal from a human body, for use for a scheduled purpose, of any relevant material 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) relevant material 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) relevant material 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) relevant material 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 relevant material which—

(i) has been removed from a person's body for the purposes of his 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.

(2) Without prejudice to the generality of subsection (1)(a) and (b), the activities within the remit of the Authority include, in particular—

(a) the carrying-out of an anatomical examination, and

(b) the making of a post-mortem examination.

(3) An activity is excluded from the remit of the Authority if—

(a) it relates to the body of a person who died before the day on which this section comes into force or to material which has come from the body of such a person, and

(b) at least one hundred years have elapsed since the date of the person's death.

(4) The Secretary of State may by order amend this section for the purpose of adding to the activities within the remit of the Authority.

(5) In this section, "relevant material", in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood.

15 General functions

The Authority shall have the following general functions—

(a) maintaining a statement of the general principles which it considers should be followed—

(i) in the carrying-on of activities within its remit, and

(ii) in the carrying-out of its functions in relation to such activities;

(b) providing in relation to activities within its remit such general oversight and guidance as it considers appropriate;

(c) superintending, in relation to activities within its remit, compliance with—

(i) requirements imposed by or under Part 1 or this Part, and

(ii) codes of practice under this Act;

(d) providing to the public, and to persons carrying on activities within its remit, such information and advice as it considers appropriate about the nature and purpose of such activities;

(e) monitoring developments relating to activities within its remit and advising the Secretary of State, the National Assembly for Wales and the relevant Northern Ireland department on issues relating to such developments;

(f) advising the Secretary of State, the National Assembly for Wales or the relevant Northern Ireland department on such other issues relating to activities within its remit as he, the Assembly or the department may require.

Licensing

16 Licence requirement

(1) No person shall do an activity to which this section applies otherwise than under the authority of a licence granted 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 relevant material 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) relevant material 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) relevant material which has come from the body of a deceased person.

(3) The Secretary of State may by regulations specify circumstances in which storage of relevant material by a person who intends to use it for a scheduled purpose is excepted from subsection (2)(e)(ii).

(4) 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 material which has come from the body of such a person, and

(b) at least one hundred years have elapsed since the date of the person's death.

(5) The Secretary of State 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.

(6) Schedule 3 (which makes provision about licences for the purposes of this section) has effect.

(7) In subsection (2)—

(a) references to storage do not include storage which is incidental to transportation, and

(b) "relevant material", in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood.

17 Persons to whom licence applies

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 Authority 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).

18 Duty of the designated individual

It shall be 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—

(a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity,

(b) that suitable practices are used in the course of carrying on that activity, and

(c) that the conditions of the licence are complied with.

19 Right to reconsideration of licensing decisions

(1) If an application for the grant, revocation or variation of a licence is refused, the applicant may require the Authority to reconsider the decision.

(2) If a licence is—

(a) revoked under paragraph 7(2) of Schedule 3, or

(b) varied under paragraph 8(3) or (5) of that Schedule,

the holder of the licence, or the designated individual, may require the Authority to reconsider the decision.

(3) If an application for the grant, or revocation, of permission for the purposes of an authorisation condition is refused, the applicant may require the Authority to reconsider the decision.

(4) If permission for the purposes of an authorisation condition is revoked under paragraph 12(4)(b) of Schedule 3, any of—

(a) the individual concerned,

(b) the holder of the licence, and

(c) the designated individual,

may require the Authority to reconsider the decision.

(5) The right under subsection (1) or (2) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under paragraph 11 of Schedule 3.

(6) The right under subsection (3) or (4) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under paragraph 12 of Schedule 3.

(7) Subsections (1) to (4) do not apply to a decision on reconsideration.

(8) In this section, "authorisation condition" means a condition of a licence where—

(a) the licence is one to which paragraph 3 of Schedule 3 applies, and

(b) the condition is the one required in the licence by sub-paragraph (2) of that paragraph.

20 Appeals committees

(1) The Authority shall maintain one or more committees to carry out its functions in pursuance of notices under section 19.

(2) A committee under subsection (1) is referred to in this Part as an appeals committee.

(3) An appeals committee shall consist of not less than five members of the Authority.

(4) The quorum for an appeals committee shall be three.

21 Procedure on reconsideration

(1) Reconsideration shall be by way of fresh decision.

(2) On reconsideration—

(a) the person by whom reconsideration is required ("the appellant") shall be entitled to require that he or his representative be given an opportunity to appear before and be heard by the appeals committee dealing with the matter,

(b) at any meeting at which such an opportunity is given, the person who made the decision which is the subject of reconsideration shall be entitled to appear and be heard in person or by a representative, and

(c) the appeals committee dealing with the matter shall consider any written representations received from the appellant or the person who made the decision which is the subject of reconsideration.

(3) The appeals committee by which a decision is reconsidered in pursuance of a notice under section 19 shall give the appellant notice of its decision.

(4) If on reconsideration an appeals committee upholds the previous decision, the notice under subsection (3) shall include a statement of the reasons for the appeals committee's decision.

(5) The Authority may by regulations make such other provision about procedure in relation to reconsideration as it thinks fit.

(6) Where reconsideration of a decision—

(a) is required under section 19(2) or (4) by only one of two persons by whom it could have been required, or

(b) is required under section 19(4) by only one or two of three persons by whom it could have been required,

it shall be treated for the purposes of this section as required by both or (as the case may be) all of them.

(7) In this section, "reconsideration" means reconsideration in pursuance of a notice under section 19.

22 Appeal on point of law

A person aggrieved by a decision on reconsideration in pursuance of a notice under section 19 may appeal to the High Court on a point of law.

23 Conduct of licensed activities

(1) Directions may impose requirements in relation to the conduct of the activity which a licence authorises to be carried on.

(2) Directions under subsection (1) may be given in relation to licences generally, licences of a particular description or a particular licence.

(3) A person shall comply with a requirement imposed by directions under subsection (1) if it is applicable to him.

24 Changes of licence circumstance

(1) Directions 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 he 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 he 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.

25 Breach of licence requirement

(1) A person who contravenes section 16(1) commits an offence, unless he reasonably believes—
(a) that what he does is not an activity to which section 16 applies, or
(b) that he acts under the authority of a licence.

(2) A person guilty of an offence under subsection (1) shall be liable—
(a) on summary conviction to a fine not exceeding the statutory maximum;
(b) on conviction on indictment—
(i) to imprisonment for a term not exceeding 3 years, or
(ii) to a fine, or
(iii) to both.

Codes of practice

26 Preparation of codes

(1) The Authority may prepare and issue codes of practice for the purpose of—
(a) giving practical guidance to persons carrying on activities within its remit, and
(b) laying down the standards expected in relation to the carrying-on of such activities.

(2) The Authority shall deal under subsection (1) 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 relevant material of which the body consists or which it contains;
(h) the removal from a human body, for use for a scheduled purpose, of any relevant material 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) relevant material 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 9;
(k) the import, and the export, of—
  (i) the body of a deceased person, or
  (ii) relevant material which has come from a human body,
for use for a scheduled purpose;
(l) the disposal of relevant material 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 9.

(3) In dealing under subsection (1) with the matters mentioned in subsection (2)(h) and (i), the Authority shall, in particular, deal with consent.

(4) The Authority shall—
(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 Authority shall—
(a) consult such persons as it considers appropriate,
(b) if the code of practice relates to Wales, consult the National Assembly for Wales, and
(c) if the code of practice relates to Northern Ireland, consult the relevant Northern Ireland department.

(6) The Authority shall 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 directions.

(8) Codes of practice under this section may make different provision in relation to England, Wales and Northern Ireland respectively.

27 Provision with respect to consent

(1) The duty under section 26(3) shall have effect, in particular, to require the Authority to lay down the standards expected in relation to the obtaining of consent where consent falls by virtue of section 2(7)(b)(ii) or 3(6)(c) 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 (8).

(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 Authority to be exceptional.

(4) The qualifying relationships for the purpose of sections 2(7)(b)(ii) and 3(6)(c) should be ranked in the following order—

(a) spouse 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.

(5) Relationships in the same paragraph of subsection (4) should be accorded equal ranking.

(6) Consent should be obtained from the person whose relationship to the person concerned is accorded the highest ranking in accordance with subsections (4) and (5).

(7) If the relationship of each of two or more persons to the person concerned is accorded equal highest ranking in accordance with subsections (4) and (5), it is sufficient to obtain the consent of any of them.

(8) In applying the principles set out above, a person's relationship shall be left out of account if—
(a) he does not wish to deal with the issue of consent,
(b) he 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 him within the time available if consent in relation to the activity is to be acted on.

(9) The Secretary of State may by order amend subsection (4).

28 Effect of codes

(1) A failure on the part of any person to observe any provision of a code of practice under section 26 shall not of itself render the person liable to any proceedings.

(2) The Authority 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 26, 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.

29 Approval of codes

(1) The Authority may not issue a code of practice under section 26 that deals with a matter mentioned in any of paragraphs (a) to (c) and (e) to (j) of subsection (2) of that section unless—
(a) a draft of it has been sent to and approved by the Secretary of State and laid by him before both Houses of Parliament, and
(b) the 40-day period has elapsed without either House resolving not to approve the draft.

(2) Before approving a draft code of practice sent to him under subsection (1), the Secretary of State shall—
(a) if the code relates to Wales, consult the National Assembly for Wales, and

(b) if the code relates to Northern Ireland, consult the relevant Northern Ireland department.

(3) If the Secretary of State approves a draft code of practice sent to him under subsection (1)—

(a) if the code relates to Wales, he shall send a copy of it to the National Assembly for Wales, and

(b) if the code relates to Northern Ireland, he shall send a copy of it to the relevant Northern Ireland department.

(4) If the Secretary of State does not approve a draft sent to him under subsection (1), he shall give reasons to the Authority.

(5) The relevant Northern Ireland department shall lay before the Northern Ireland Assembly any document which it receives under subsection (3)(b).

(6) In subsection (1)(b), "40-day period", in relation to the draft of a code of practice, means—

(a) if the draft is laid before one House on a day later than the day on which it is laid before the other House, the period of 40 days beginning with the later of the two days, and

(b) in any other case, the period of 40 days beginning with the day on which the draft is laid before each House,

no account being taken of any period during which Parliament is dissolved or prorogued or during which both Houses are adjourned for more than 4 days.

Anatomy

30 Possession of anatomical specimens away from licensed premises

(1) Subject to subsections (2) to (6), a person commits an offence if—

(a) he has possession of an anatomical specimen, and

(b) the specimen is not on premises in respect of which an anatomy licence is in force.

(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 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 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 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) A person guilty of an offence under subsection (1) shall be liable—
(a) on summary conviction to a fine not exceeding the statutory maximum;
(b) on conviction on indictment—
(i) to imprisonment for a term not exceeding 3 years, or
(ii) to a fine, or
(iii) to both.

(8) In this section—
"anatomy licence" means a licence 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.

31 Possession of former anatomical specimens away from licensed premises

(1) Subject to subsections (2) to (5), a person commits an offence if—
(a) he 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.

(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 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 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) A person guilty of an offence under subsection (1) shall be liable—
  (a) on summary conviction to a fine not exceeding the statutory maximum;
  (b) on conviction on indictment—
    (i) to imprisonment for a term not exceeding 3 years, or
    (ii) to a fine, or
    (iii) to both.

(7) In this section, "storage licence" means a licence authorising the storage, for use for a scheduled purpose, of relevant material which has come from a human body.

Trafficking

32 Prohibition of commercial dealings in human material for transplantation

(1) A person commits an offence if he—
  (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;
  (e) takes part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.

(2) Without prejudice to subsection (1)(b) and (c), a person commits an offence if he 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).

(3) A person who engages in an activity to which subsection (1) or (2) applies does not commit an offence under that subsection if he is designated by the Authority as a person who may lawfully engage in the activity.

(4) A person guilty of an offence under subsection (1) shall be liable—
  (a) on summary conviction—
    (i) to imprisonment for a term not exceeding 12 months, or
    (ii) to a fine not exceeding the statutory maximum, or
    (iii) to both;
  (b) on conviction on indictment—
    (i) to imprisonment for a term not exceeding 3 years, or

(ii) to a fine, or
(iii) to both.

(5) A person guilty of an offence under subsection (2) shall be liable on summary conviction—
(a) to imprisonment for a term not exceeding 51 weeks, or
(b) to a fine not exceeding level 5 on the standard scale, or
(c) to both.

(6) For the purposes of subsections (1) and (2), payment in money or money's worth to the holder of a licence shall be treated as not being 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.

(7) 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 (6) has effect, or
(c) any expenses or loss of earnings incurred by the person from whose body the material comes so far as reasonably and directly attributable to his supplying the material from his body.

(8) 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 (9).

(9) The following kinds of material are excepted—
(a) gametes,
(b) embryos, and
(c) material which is the subject of property because of an application of human skill.

(10) 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 (9),
for use for the purpose of transplantation, the body shall be treated as controlled material for the purposes of this section.

(11) 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.

Transplants

33 Restriction on transplants involving a live donor

(1) Subject to subsections (3) and (5), a person commits an offence if—

(a) he 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 he removes the material, he knows, or might reasonably be expected to know, that the person from whose body he removes the material is alive.

(2) Subject to subsections (3) and (5), a person commits an offence if—

(a) he uses for the purpose of transplantation any transplantable material which has come from the body of a living person, and

(b) when he does so, he knows, or might reasonably be expected to know, that the transplantable material has come from the body of a living person.

(3) The Secretary of State may by regulations provide that subsection (1) or (2) shall not apply in a case where—

(a) the Authority is satisfied—

(i) that no reward has been or is to be given in contravention of section 32, 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) shall include provision for decisions of the Authority 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, a person does not commit an offence under that subsection if he reasonably believes that the exception applies.

(6) A person guilty of an offence under this section is liable on summary conviction—

(a) to imprisonment for a term not exceeding 51 weeks, or

(b) to a fine not exceeding level 5 on the standard scale, or

(c) to both.

(7) In this section—

"reward" has the same meaning as in section 32;

"transplantable material" means material of a description specified by regulations made by the Secretary of State.

34 Information about transplant operations

(1) The Secretary of State may make regulations requiring such persons as may be specified in the regulations to supply to such authority as may be so specified such information as may be so specified with respect to transplants that have

been or are proposed to be carried out using transplantable material removed from a human body.

(2) Any such authority shall keep a record of information supplied to it in pursuance of regulations under this section.

(3) A person commits an offence if—

(a) he fails without reasonable excuse to comply with regulations under this section, or

(b) in purported compliance with such regulations, he knowingly or recklessly supplies information which is false or misleading in a material respect.

(4) A person guilty of an offence under subsection (3)(a) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(5) A person guilty of an offence under subsection (3)(b) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(6) In this section, "transplantable material" has the same meaning as in section 33.

General

35 Agency arrangements and provision of services

(1) Arrangements may be made between the Authority and a government department, a public authority or the holder of a public office ("the other authority") for—

(a) any functions of the Authority 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 Authority.

(2) Arrangements under subsection (1)(a) shall not affect responsibility for the carrying-out of the Authority's functions.

(3) Subsection (1)(a) shall not apply to functions of making subordinate legislation (within the meaning of the Interpretation Act 1978 (c. 30)).

36 Annual report

(1) The Authority shall prepare—

(a) a report for the first twelve months of its existence, and

(b) a report for each succeeding period of twelve months.

(2) A report under this section shall deal with the activities of the Authority in the period to which the report relates.

(3) The Authority shall send each report under this section—

(a) to the Secretary of State,

(b) to the National Assembly for Wales, and

(c) to the relevant Northern Ireland department,

as soon as practicable after the end of the period to which the report relates.

(4) The Secretary of State shall lay a copy of each report received by him under this section before each House of Parliament.

(5) The relevant Northern Ireland department shall lay a copy of each report received by it under this section before the Northern Ireland Assembly.

37 Directions

(1) The Authority may give directions for any purpose for which directions may be given under this Part.

(2) Any power under this Part to give directions includes power to vary or revoke directions given in previous exercise of the power.

(3) Any power under this Part to give directions is exercisable by instrument in writing.

(4) Directions under this Part to a particular person shall be given by serving notice of the directions on the person.

(5) Directions under this Part 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 Authority 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 Authority to be general directions may be given by publishing them as mentioned in subsection (5)(b).

(7) This section does not apply to directions under Schedule 2.

38 Duties in relation to carrying out functions

(1) The Authority must carry out its functions effectively, efficiently and economically.

(2) In carrying out its functions, the Authority 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).

Exceptions

39 Criminal justice purposes

(1) Subject to subsection (2), nothing in section 14(1) or 16(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 14(1) or 16(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 relevant material 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 United Kingdom 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 United Kingdom.

(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 a part of the United Kingdom or of a country or territory outside the United Kingdom),

(b) is, or corresponds to, any conduct which, if it all took place in any one part of the United Kingdom, would constitute one or more criminal offences, or

(c) constitutes one or more offences of a kind triable by court-martial under the Army Act 1955 (3 & 4 Eliz. 2 c. 18), the Air Force Act 1955 (3 & 4 Eliz. 2 c. 19) or the Naval Discipline Act 1957 (c. 53).

40 Religious relics

(1) This section applies—

(a) to the use of—

(i) the body of a deceased person, or

(ii) relevant material 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) relevant material 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 14(1) and 16(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.

Supplementary

41 Interpretation of Part 2

(1) In this Part—

"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);

"appeals committee" has the meaning given by section 20(2);

"designated individual", in relation to a licence, means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on;

"export" means export from England, Wales or Northern Ireland to a place outside England, Wales and Northern Ireland;

"import" means import into England, Wales or Northern Ireland from a place outside England, Wales and Northern Ireland;

"scheduled purpose" means a purpose specified in Schedule 1.

(2) In this Part, references to the carrying-out of an anatomical examination are to the carrying-out of a macroscopic examination by dissection for anatomical purposes of the body of a deceased person, and, where parts of the body of a deceased person are separated in the course of such an examination, include the carrying-out of a macroscopic examination by dissection of the parts for those purposes.

(3) In this Part, references to a person to whom a licence applies are to a person to whom the authority conferred by the licence extends (as provided by section 17).

PART 3

MISCELLANEOUS AND GENERAL

Miscellaneous

42 Power of Human Tissue Authority to assist other public authorities

(1) The Authority may if it thinks it appropriate to do so provide assistance to any other public authority in the United Kingdom for the purpose of the exercise by that authority of its functions.

(2) Assistance provided by the Authority under this section may be provided on such terms, including terms as to payment, as it thinks fit.

43 Preservation for transplantation

(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 shall be 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) shall only extend—

(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) shall extend 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) shall be treated—

(a) for the purposes of Part 1, as not being an activity to which section 1(1) applies;

(b) for the purposes of Part 2, as not being an activity to which section 16 applies.

(6) In this section, "body" means the body of a deceased person.

44 Surplus tissue

(1) It shall be lawful for material to which subsection (2) or (3) applies to be dealt with as 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 his—

(a) receiving medical treatment,

(b) undergoing diagnostic testing, or

(c) participating in research.

(3) This subsection applies to any relevant material 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.

45 Non-consensual analysis of DNA

(1) A person commits an offence if—

(a) he 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) he 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 force and at least one hundred 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.

(3) A person guilty of an offence under this section—

(a) is liable on summary conviction to a fine not exceeding the statutory maximum;

(b) is liable on conviction on indictment—

(i) to imprisonment for a term not exceeding 3 years, or

(ii) to a fine, or

(iii) to both.

(4) Schedule 4 (which makes provision for the interpretation of "qualifying consent" and "use for an excepted purpose" in subsection (1)(a)) has effect.

(5) In this section (and Schedule 4)—

"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.

46 Power to give effect to Community obligations

(1) The Secretary of State may by regulations amend this Act—

(a) for the purpose of implementing a relevant obligation or enabling a relevant obligation to be implemented, or

(b) for the purpose of dealing with matters arising out of or related to a relevant obligation.

(2) The power under subsection (1)—

(a) includes (in particular) power to add or omit provisions, and

(b) includes power consequentially to amend or repeal any other enactment and any instrument made under an enactment.

(3) In this section, "relevant obligation" means a Community obligation of the United Kingdom relating to material which consists of, includes or is derived from human cells.

47 Power to de-accession human remains

(1) This section applies to the following bodies—

The Board of Trustees of the Armouries

The Trustees of the British Museum

The Trustees of the Imperial War Museum

The Board of Governors of the Museum of London

The Trustees of the National Maritime Museum

The Board of Trustees of the National Museums and Galleries on Merseyside

The Trustees of the Natural History Museum
The Board of Trustees of the Science Museum
The Board of Trustees of the Victoria and Albert Museum.

(2) Any body to which this section applies may transfer from their collection any human remains which they reasonably believe to be remains of a person who died less than one thousand years before the day on which this section comes into force if it appears to them to be appropriate to do so for any reason, whether or not relating to their other functions.

(3) If, in relation to any human remains in their collection, it appears to a body to which this section applies—

(a) that the human remains are mixed or bound up with something other than human remains, and

(b) that it is undesirable, or impracticable, to separate them,

the power conferred by subsection (2) includes power to transfer the thing with which the human remains are mixed or bound up.

(4) The power conferred by subsection (2) does not affect any trust or condition subject to which a body to which this section applies holds anything in relation to which the power is exercisable.

(5) The power conferred by subsection (2) is an additional power.

General

48 Powers of inspection, entry, search and seizure

Schedule 5 (which makes provision about powers of inspection, entry, search and seizure for the purposes of this Act) has effect.

49 Offences by bodies corporate

(1) Where an offence under this Act is committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of—

(a) any director, manager, secretary or other similar officer of the body corporate, or

(b) any person who was purporting to act in any such capacity,

he (as well as the body corporate) commits the offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, subsection (1) applies in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(3) Where an offence under this Act is committed by a Scottish partnership and is proved to have been committed with the consent or connivance of a partner, or to be attributable to any neglect on the part of a partner, he (as well as the partnership) commits the offence and shall be liable to be proceeded against and punished accordingly.

(4) In subsection (3), "partner" includes a person purporting to act as a partner.

50 Prosecutions

No proceedings for an offence under section 5, 32 or 33 shall be instituted—

(a) in England and Wales, except by or with the consent of the Director of Public Prosecutions;

(b) in Northern Ireland, except by or with the consent of the Director of Public Prosecutions for Northern Ireland.

51 Offences: Northern Ireland

(1) This Act has effect in relation to Northern Ireland with the modifications specified in subsections (2) and (3).

(2) In sections 32(5)(a) and 33(6)(a), for "51 weeks" there is substituted "6 months".

(3) In section 32(4)(a)(i), for "12 months" there is substituted "6 months".

52 Orders and regulations

(1) Any power to make orders or regulations under this Act includes power—

(a) to make different provision for different cases, and

(b) to make incidental, supplementary, consequential or transitional provision or savings.

(2) Any power to make orders or regulations under this Act is exercisable by statutory instrument.

(3) A statutory instrument containing an order or regulations under this Act, except sections 1(11), 6, 7(4), 10(9), 14(4), 16(5), 27(9), 33(3) and (7), 46(1) and 54(10) and paragraphs 6(2), 12(2) and 13 of Schedule 4, made by the Secretary of State shall be subject to annulment in pursuance of a resolution of either House of Parliament.

(4) No order under section 1(11), 10(9), 14(4), 27(9) or 54(10) or paragraph 13 of Schedule 4, and no regulations under section 6, 7(4), 16(5), 33(3) or (7) or 46(1) or paragraph 6(2) or 12(2) of Schedule 4, shall be made unless a draft of the statutory instrument containing it, or them, has been laid before and approved by a resolution of each House of Parliament.

(5) Subsections (1) and (2) do not apply to any power of a court.

(6) Subsections (1) to (3) do not apply to orders under section 58 or 60.

(7) The power under section 14(4) or 16(5)—

(a) so far as relating to museums in Wales, may only be exercised with the consent of the National Assembly for Wales, and

(b) so far as relating to museums in Northern Ireland, may only be exercised with the consent of the Department of Culture, Arts and Leisure.

(8) The Secretary of State shall consult the National Assembly for Wales and the relevant Northern Ireland department before acting under any of the following provisions—

section 1(9)(a) and (11);

section 4(10)(b);

section 6;

section 7(4);
section 8(4)(d);
section 10(9);
section 14(4);
section 16(3) and (5);
section 27(9);
section 33(3) and (7);
section 34(1);
section 46(1);
section 54(10);
paragraphs 6(2), 10(b), 12(2) and 13 of Schedule 4;
paragraph 4(5) of Schedule 5.

(9) Before acting—
(a) under section 54(10) in order to amend section 54(9) so far as having effect for the purposes of Schedule 4, or
(b) under paragraph 6(2), 10(b), 12(2) or 13 of Schedule 4,
the Secretary of State shall also consult the Scottish Ministers.

(10) Before acting under any of the following provisions, the Secretary of State shall also consult such other persons as he considers appropriate—
section 1(11);
section 6;
section 7(4);
section 10(9);
section 14(4);
section 16(5);
section 27(9);
section 33(3) and (7);
section 46(1);
section 54(10);
paragraphs 6(2), 12(2) and 13 of Schedule 4.

53 "Relevant material"

(1) In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.

(2) In this Act, references to relevant material from a human body do not include—
(a) embryos outside the human body, or
(b) hair and nail from the body of a living person.

54 General interpretation

(1) 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;
"the Authority" has the meaning given by section 13(1);

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

"licence" means a licence under paragraph 1 of Schedule 3;

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

"parental responsibility"—

(a) in relation to England and Wales, has the same meaning as in the Children Act 1989 (c. 41), and

(b) in relation to Northern Ireland, has the same meaning as in the Children (Northern Ireland) Order 1995 (S.I. 1995/755 (N.I. 2));

"relevant Northern Ireland department" means the Department of Health, Social Services and Public Safety.

(2) 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.

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

(4) In this Act, references to decent disposal include, in relation to disposal of material which has come from a human body, disposal as waste.

(5) 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.

(6) Subsections (1) and (4) of section 1 of the Human Fertilisation and Embryology Act 1990 (c. 37) (definitions of "embryo" and "gametes") have effect for the purposes of this Act as they have effect for the purposes of that Act (other than that section).

(7) For the purposes of this Act, material shall not be regarded as from a human body if it is created outside the human body.

(8) For the purposes of this Act, except section 49, 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.

(9) The following are qualifying relationships for the purposes of this Act, spouse, partner, parent, child, brother, sister, grandparent, grandchild, child of a brother or sister, stepfather, stepmother, half-brother, half-sister and friend of long standing.

(10) The Secretary of State may by order amend subsection (9).

55 Financial provisions

There shall be paid out of money provided by Parliament—

(a) any expenditure incurred by the Secretary of State 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.

56 Consequential amendments

Schedule 6 (consequential amendments) has effect.

57 Repeals and revocations

The enactments and instruments specified in Schedule 7 are hereby repealed or revoked to the extent specified.

58 Transition

(1) In relation to an offence committed before the commencement of section 154(1) of the Criminal Justice Act 2003 (c. 44), the reference in section 32(4)(a)(i) to 12 months is to be read as a reference to 6 months.

(2) In relation to an offence committed before the commencement of section 281(5) of the Criminal Justice Act 2003, the reference in each of sections 32(5)(a) and 33(6)(a) to 51 weeks is to be read as a reference to 6 months.

(3) The Secretary of State may by order made by statutory instrument make in connection with the coming into force of any provision of this Act such transitional provision or savings as he considers necessary or expedient.

(4) The power under subsection (3) includes power to make different provision for different cases.

(5) Before making provision under subsection (3) in connection with the coming into force in England and Wales of any provision of this Act, except section 47, the Secretary of State shall consult the National Assembly for Wales.

(6) Before making provision under subsection (3) in connection with the coming into force in Northern Ireland of any provision of this Act, except section 47, the Secretary of State shall consult the relevant Northern Ireland department.

(7) Before making provision under subsection (3) in connection with the coming into force in Scotland of any provision of this Act, except section 47, the Secretary of State shall consult the Scottish Ministers.

59 Extent

(1) Subject to the following provisions, this Act extends to England and Wales and Northern Ireland only.

(2) Sections 58(1), (2) and (5) and 60(3) extend to England and Wales only.

(3) Sections 51(1) to (3), 58(6) and 60(4) extend to Northern Ireland only.

(4) The following provisions also extend to Scotland—

(a) sections 45(1) to (3) and (5) and 47,

(b) section 49 so far as having effect for the purposes of section 45,

(c) section 52 so far as relating to orders under section 54(10) or paragraph 13 of Schedule 4 or regulations under paragraph 6(2) or 12(2) of that Schedule,

(d) section 54(2)(a), (3), (8) and (9) so far as having effect for the purposes of Schedule 4,

(e) section 54(6) and (7) so far as having effect for the purposes of section 45 or Schedule 4,

(f) sections 54(10) and 58(3) and (4), this section and sections 60(1) and (2) and 61, and

(g) Schedule 4, except paragraphs 3 and 9(2) to (5), and section 45(4) so far as relating thereto.

(5) The following provisions extend to Scotland only—

(a) sections 58(7) and 60(5),

(b) paragraphs 3 and 9(4) and (5) of Schedule 4, and section 45(4) so far as relating thereto, and

(c) paragraphs 2 and 4 of Schedule 6, and section 56 so far as relating thereto.

(6) Subject to subsection (5), any amendment made by this Act has the same extent as the enactment to which it relates.

(7) Subject to subsection (8), any repeal or revocation made by this Act has the same extent as the enactment or instrument to which it relates.

(8) Except as provided by subsection (9), the repeals of the following do not extend to Scotland—

(a) the Human Tissue Act 1961 (c. 54),

(b) the Anatomy Act 1984 (c. 14),

(c) the Corneal Tissue Act 1986 (c. 18), and

(d) the Human Organ Transplants Act 1989 (c. 31).

(9) The repeals of the following provisions do extend to Scotland—

(a) in section 1(4A)(b) of the Human Tissue Act 1961, the words ", Primary Care Trust";

(b) in section 1(10) of that Act—

(i) paragraph (a) of the definition of "health authority",

(ii) in the definition of "NHS trust", the words "the National Health Service and Community Care Act 1990 or", and

(iii) the words after the definition of that expression;

(c) section 4(5) of the Anatomy Act 1984;

(d) in the Human Organ Transplants Act 1989—

(i) in section 1, the words "in Great Britain", in the first and third places where they occur,

(ii) in sections 2 and 3, the words "in Great Britain", in each place, and

(iii) sections 5 and 6.

60 Commencement

(1) The following provisions shall come into force on the day on which this Act is passed—

this section, and

sections 58(3) to (7), 59 and 61.

(2) The remaining provisions of this Act shall come into force on such day as the Secretary of State may appoint by order made by statutory instrument, and different days may be so appointed for different purposes.

(3) Before exercising the power under subsection (2) in relation to the coming into force in England and Wales of any provision of this Act, except section 47, the Secretary of State shall consult the National Assembly for Wales.

(4) Before exercising the power under subsection (2) in relation to the coming into force in Northern Ireland of any provision of this Act, except section 47, the Secretary of State shall consult the relevant Northern Ireland department.

(5) Before exercising the power under subsection (2) in relation to the coming into force in Scotland of any provision of this Act, except section 47, the Secretary of State shall consult the Scottish Ministers.

(6) No day may be appointed under subsection (2) for the coming into force of section 5 or 8 which is earlier than the end of the period of three months beginning with the day on which the Authority first issues a code of practice dealing with the matters mentioned in section 26(2)(h) and (i).

(7) If the Authority first issues a code of practice dealing with one of the matters mentioned in subsection (6) before it first issues a code of practice dealing with the other, that subsection shall have effect as if the three month period were one beginning with the later of—

(a) the day on which the Authority first issues a code of practice dealing with the matter mentioned in section 26(2)(h), and

(b) the day on which the Authority first issues a code of practice dealing with the matter mentioned in section 26(2)(i).

61 Short title

This Act may be cited as the Human Tissue Act 2004.

SCHEDULES

SCHEDULE 1

Section 1

SCHEDULED PURPOSES

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 him.

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

Section 13

THE HUMAN TISSUE AUTHORITY

Membership

1 (1) The Authority shall consist of—

(a) a chairman appointed by the Secretary of State,
(b) such number of other members appointed by the Secretary of State as the Secretary of State thinks fit,
(c) a member appointed by the National Assembly for Wales, and
(d) a member appointed by the relevant Northern Ireland department.

(2) The Secretary of State shall exercise his power to appoint members of the Authority to secure that at all times not less than half of the members are persons who do not have, and have not had, a professional interest in any of the kinds of activity within the remit of the Authority.

Disqualification

2 A person is disqualified for being appointed as chairman of the Authority if he has, or has had, a professional interest in any of the kinds of activity within the remit of the Authority.

3 (1) A person is disqualified for being appointed as chairman or other member of the Authority if—
(a) he is the subject of a bankruptcy restrictions order or interim order,
(b) a bankruptcy order has been made against him by a court in Northern Ireland, his estate has been sequestrated by a court in Scotland or, under the law of Northern Ireland or Scotland, he has made a composition or arrangement with, or granted a trust deed for, his creditors, or
(c) in the last five years he has been convicted in the United Kingdom, the Channel Islands or the Isle of Man of an offence and has had a qualifying sentence passed on him.

(2) Where a person is disqualified under sub-paragraph (1)(b) because a bankruptcy order has been made against him or his estate has been sequestrated, the disqualification shall cease—
(a) on his obtaining a discharge, or
(b) if the bankruptcy order is annulled or the sequestration of his estate is recalled or reduced, on the date of that event.

(3) Where a person is disqualified under sub-paragraph (1)(b) because of his having made a composition or arrangement with, or granted a trust deed for, his creditors, the disqualification shall cease—
(a) at the end of the period of five years beginning with the date on which the terms of the deed of composition or arrangement or trust deed are fulfilled, or
(b) if, before then, he pays his debts in full, on the date on which the payment is completed.

(4) For the purposes of sub-paragraph (1)(c), the date of conviction shall be taken to be the ordinary date on which the period allowed for making an appeal or application expires or, if an appeal or application is made, the date on which the appeal or application is finally disposed of or abandoned or fails by reason of its non-prosecution.

(5) In sub-paragraph (1)(c), the reference to a qualifying sentence is to a sentence of imprisonment for a period of not less than three months (whether suspended or not) without the option of a fine.

Tenure of office

4 Subject to the following provisions of this Schedule, the chairman and other members of the Authority shall hold and vacate office in accordance with the terms of their respective appointments.

5 (1) The terms of appointment of the chairman and other members of the Authority shall be such as the Secretary of State may determine, subject to sub-paragraph (2).

(2) Appointment as chairman or other member shall be for a term not exceeding three years.

6 Previous service as chairman or other member of the Authority does not affect a person's eligibility for appointment to either office.

7 A person holding office as chairman or other member of the Authority may resign that office by giving notice in writing to the person who appointed him.

8 A person holding office as chairman or other member of the Authority shall cease to hold that office if he ceases to be qualified for appointment to it.

9 A person may be removed from office as chairman or other member of the Authority by the person who appointed him if that person is satisfied that he—

(a) has been absent from meetings of the Authority for six consecutive months, or longer, without the permission of the Authority, or

(b) is unable or unfit to carry out his functions as chairman or other member.

Remuneration and pensions of members

10 (1) The Authority may pay to the chairman or any of the other members of the Authority such remuneration as the Secretary of State may determine.

(2) The Authority may pay, or make provision for paying, to or in respect of the chairman or any of the other members of the Authority such pensions, allowances, fees, expenses or gratuities as the Secretary of State may determine.

(3) The Authority may make a payment to a person who ceases to hold office as chairman or other member of the Authority otherwise than on the expiry of his term of office if it appears to the Secretary of State that there are special circumstances which make it right for that person to receive compensation.

(4) A payment under sub-paragraph (3) shall be of such amount as the Secretary of State may determine.

Staff

11 The Authority may appoint such staff as it considers appropriate, on such terms and conditions as it may determine.

Proceedings

12 Subject to any provision of this Act, the Authority may regulate its own procedure (including quorum).

13 The validity of any proceedings of the Authority shall not be affected by—

(a) any vacancy in the office of—

(i) chairman,

(ii) member appointed by the National Assembly for Wales, or

(iii) member appointed by the relevant Northern Ireland department,

(b) any defect in a person's appointment as chairman or other member, or

(c) the composition for the time being of the membership of the Authority.

Members' interests

14 (1) The Authority shall establish and maintain a system for the declaration and registration of private interests of its members.

(2) The Authority shall publish entries recorded in the register of members' interests.

Finance

15 The Secretary of State may out of money provided by Parliament make payments to the Authority of such amounts, at such times and on such conditions (if any) as he considers appropriate.

Accounts and audit

16 (1) The Authority shall keep proper accounts and proper records in relation to its accounts.

(2) The Authority shall prepare a statement of accounts in respect of each of its financial years.

(3) Any such statement of accounts must comply with any directions given by the Secretary of State with the approval of the Treasury as to—

(a) the information to be contained in it,

(b) the manner in which that information is to be presented, and

(c) the methods and principles according to which the statement is to be prepared.

(4) The Authority shall send a copy of each statement of accounts required by sub-paragraph (2) to—

(a) the Secretary of State,

(b) the National Assembly for Wales,

(c) the relevant Northern Ireland department, and

(d) the Comptroller and Auditor General,

before the end of such period after the end of the financial year to which the statement relates as the Secretary of State may specify by notice given to the Authority.

(5) The relevant Northern Ireland department shall lay before the Northern Ireland Assembly each statement of accounts received by it under sub-paragraph (4).

(6) The Comptroller and Auditor General shall—

(a) examine, certify and report on each statement of accounts received by him under sub-paragraph (4), and

(b) lay a copy of each such statement of accounts, and of his report on it, before each House of Parliament.

(7) The power under sub-paragraph (3) to give directions includes power to vary or revoke directions given in previous exercise of the power.

(8) In this paragraph, "financial year" means—

(a) the period beginning with the date on which the Authority is established and ending with the next 31st March, and

(b) each successive period of 12 months ending with 31st March.

Instruments

17 The application of the seal of the Authority shall be authenticated by the signature of any member of the Authority or of any other person who has been authorised for the purpose by the Authority, whether generally or specially.

18 A document purporting—

(a) to be duly executed under the seal of the Authority, or

(b) to be signed on its behalf,

shall be received in evidence and be taken, without further proof, to be so executed or signed unless the contrary is shown.

Status

19 (1) The Authority is not to be regarded as the servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown.

(2) The property of the Authority is not to be regarded as property of, or property held on behalf of, the Crown.

Supplementary powers

20 The Authority may do anything which is calculated to facilitate, or is conducive or incidental to, the carrying-out of its functions, but may not borrow money.

21 The Authority may delegate any of its functions (to such extent as it may determine)—

(a) to any member of the Authority,

(b) to any member of the staff of the Authority, or

(c) to a committee consisting of persons each of whom is—

(i) a member of the Authority, or

(ii) a member of the staff of the Authority.

Application of Statutory Instruments Act 1946

22 The Statutory Instruments Act 1946 (c. 36) shall apply to any power to make orders or regulations conferred by an Act on the Authority as if the Authority were a Minister of the Crown.

Public records

23 In Schedule 1 to the Public Records Act 1958 (c. 51) (definition of public records), in Part 2 of the Table at the end of paragraph 3 the following entry is inserted at the appropriate place—

"Human Tissue Authority."

Investigation by Parliamentary Commissioner

24 In Schedule 2 to the Parliamentary Commissioner Act 1967 (c. 13) (departments and authorities subject to investigation), the following entry is inserted at the appropriate place—

"Human Tissue Authority."

House of Commons Disqualification

25 In Part 2 of Schedule 1 to the House of Commons Disqualification Act 1975 (c. 24) (bodies of which all members are disqualified), the following entry is inserted at the appropriate place—

"The Human Tissue Authority."

Northern Ireland Assembly Disqualification

26 In Part 2 of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 (c. 25) (bodies of which all members are disqualified), the following entry is inserted at the appropriate place—

"The Human Tissue Authority."

Freedom of information

27 In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (c. 36) (public authorities), the following entry is inserted at the appropriate place—

"The Human Tissue Authority."

SCHEDULE 3

Section 16

LICENCES FOR THE PURPOSES OF SECTION 16

Power to grant licence

1 The Authority may on application grant a licence for the purposes of section 16.

Characteristics of licence

2 (1) A licence shall not authorise the carrying-on of more than one activity to which section 16 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 Authority 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 (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 Authority'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 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 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 (1) This paragraph applies to a licence authorising the activity mentioned in section 16(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 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 he 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 (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.

Power to impose conditions

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

Pre-conditions to grant of licence

6 (1) The Authority 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 Authority 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 18.

(4) Where the applicant for the licence is not the proposed designated individual, the Authority must be satisfied that the applicant is a suitable person to be the holder of the licence.

(5) The Authority 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.

Power to revoke licence

7 (1) The Authority may revoke a licence on application by—

(a) the holder of the licence, or

(b) the designated individual.

(2) The Authority 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 18,

(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, or

(g) it is satisfied that there has been any other material change of circumstances since the licence was granted.

Power to vary licence

8 (1) The Authority 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 Authority may vary a licence on application by—

(a) the holder of the licence, or

(b) the designated individual.

(3) The Authority 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 Authority 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.

Power to suspend licence

9 (1) Where the Authority—

(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 Authority 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 Authority to be unable because of incapacity to discharge the duty under section 18—

(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.

Procedure in relation to licensing decisions

10 (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 Authority shall give the applicant notice of the proposed decision and of the reasons for it.

(2) Before making a decision under paragraph 7(2) or 8(3) or (5), the Authority shall 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 to whom notice under sub-paragraph (1) or (2) is given has the right to require the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely—

(a) oral representations by him, or a person acting on his behalf;

(b) written representations by him.

(4) The right under sub-paragraph (3) is exercisable by giving the Authority 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 Authority may by regulations make such additional provision about procedure in relation to the carrying-out of functions under this Schedule as it thinks fit.

Notification of licensing decisions

11 (1) In the case of a decision to grant a licence, the Authority shall 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 Authority shall 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 Authority shall 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 Authority shall 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 Authority shall 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).

Permission for the purposes of the licence condition required by paragraph 3(2)

12 (1) This paragraph applies to a licence authorising the storage of anatomical specimens.

(2) The reference to the Authority's permission in the condition of the licence required by paragraph 3(2) ("the authorisation condition") is to—

(a) permission granted by the Authority 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 Authority on application by—

(i) the holder of the licence, or

(ii) the designated individual.

(3) The Authority 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 Authority 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 Authority 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 Authority 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 Authority shall give notice of the decision to the applicant.

(9) In the case of a decision to grant or revoke permission, the Authority shall 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 Authority—

(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 Authority may continue suspension under sub-paragraph (11) by giving a further notice under that sub-paragraph.

(13) Notice under sub-paragraph (11) shall be given to—

(a) the individual concerned, and

(b) the designated individual and, where different, the holder of the licence.

Applications under this Schedule

13 (1) The Authority may by regulations make provision about applications under this Schedule 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 Authority may determine.

SCHEDULE 4

Section 45

SECTION 45: SUPPLEMENTARY

PART 1

QUALIFYING CONSENT

Introductory

1 This Part of this Schedule makes provision for the interpretation of "qualifying consent" in section 45(1)(a)(i).

Qualifying consent

2 (1) In relation to analysis of DNA manufactured by the body of a person who is alive, "qualifying consent" means his consent, except where sub-paragraph (2) applies.

(2) Where—

(a) the person is a child,

(b) neither a decision of his to consent, nor a decision of his not to consent, is in force, and

(c) either he is not competent to deal with the issue of consent or, though he is competent to deal with that issue, he fails to do so,

"qualifying consent" means the consent of a person who has parental responsibility for him.

(3) In relation to analysis of DNA manufactured by the body of a person who has died an adult, "qualifying consent" means—

(a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;

(b) if paragraph (a) does not apply, the consent of a person who stood in a qualifying relationship to him immediately before he died.

(4) In relation to analysis of DNA manufactured by the body of a person who has died a child, "qualifying consent" means—

(a) if a decision of his to consent, or a decision of his not to consent, was in force immediately before he died, his consent;

(b) if paragraph (a) does not apply—

(i) the consent of a person who had parental responsibility for him immediately before he died, or

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

Application to Scotland

3 (1) In its application to Scotland, paragraph 2 has effect with the following amendments.

(2) In sub-paragraphs (2) and (4)(b)(i) and (ii), for "parental responsibility for" there is substituted "parental responsibilities in relation to".

(3) At the end there is inserted—

"(5) In this paragraph—

"adult" means a person who has attained the age of 16 years;

"child" means a person who has not attained the age of 16 years;

"parental responsibilities" has the meaning given by section 1(3) of the Children (Scotland) Act 1995 (c. 36)."

PART 2

USE FOR AN EXCEPTED PURPOSE

Introductory

4 This Part of this Schedule makes provision for the interpretation of "use for an excepted purpose" in section 45(1)(a)(ii).

Purposes of general application

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;

(c) purposes of functions of a procurator fiscal in connection with the investigation of deaths;

(d) the prevention or detection of crime;
(e) the conduct of a prosecution;
(f) purposes of national security;
(g) implementing an order or direction of a court or tribunal, including one outside the United Kingdom.

(2) For the purposes of sub-paragraph (1)(d), 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)(d) to the detection of crime includes any detection outside the United Kingdom of any crime or suspected crime.

(3) In sub-paragraph (1)(e), the reference to a prosecution includes a prosecution brought in respect of a crime in a country or territory outside the United Kingdom.

(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 a part of the United Kingdom or a country or territory outside the United Kingdom),
(b) is, or corresponds to, conduct which, if it all took place in any one part of the United Kingdom, would constitute one or more criminal offences, or
(c) constitutes one or more offences of a kind triable by court-martial under the Army Act 1955 (3 & 4 Eliz. 2 c. 18), the Air Force Act 1955 (3 & 4 Eliz. 2 c. 19) or the Naval Discipline Act 1957 (c. 53).

(5) Sub-paragraph (1)(g) shall not be taken to confer any power to make orders or give directions.

Purpose of research in connection with disorders, or functioning, of the human body

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 Secretary of State may by regulations specify circumstances in which the High Court or the Court of Session may order that this paragraph apply to bodily material.

Purposes relating to existing holdings

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;

(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.

Purposes relating to material from body of a living person

8 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.

9 (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) or an order under sub-paragraph (4) or (5), and
(b) the information may be relevant to the person for whose benefit the direction is given or order is made.

(2) If the Authority 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 Authority 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.

(4) If the Court of Session 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 is an incapable adult within the meaning of the Adults with Incapacity (Scotland) Act 2000 (asp 4),

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

(5) If the Court of Session 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 is an incapable adult within the meaning of the Adults with Incapacity (Scotland) Act 2000, 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 order that this paragraph apply to the material for the benefit of the other person.

10 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 in accordance with regulations made by the Secretary of State, 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.

Purpose authorised under section 1

11 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 England and Wales, or Northern Ireland, for that purpose of the bodily material concerned is authorised by section 1(1) or (10)(c).

Purposes relating to DNA of adults who lack capacity to consent

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—

(i) has attained the age of 18 years and, under the law of England and Wales or Northern Ireland, lacks capacity to consent to analysis of the DNA, or

(ii) under the law of Scotland, is an adult with incapacity within the meaning of the Adults with Incapacity (Scotland) Act 2000 (asp 4), and

(b) neither a decision of his to consent to analysis of the DNA for that purpose, nor a decision of his not to consent to analysis of it for that purpose, is in force.

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

Power to amend paragraphs 5, 7 and 8

13 The Secretary of State 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 5

Section 48

POWERS OF INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of statutory records

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.

Entry and inspection of licensed premises

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 Authority's functions in relation to licences.

Entry and search in connection with suspected offence

3 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—

(a) that an offence under Part 1 or 2 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,

he 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.

Execution of warrants

4 (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 him—

(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 him—

(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 Secretary of State.

(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 found them.

Seizure in the course of inspection or search

5 (1) A duly authorised person entering and inspecting premises under paragraph 2 may seize anything on the premises which he has reasonable grounds to believe may be required for purposes of the Authority'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 has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under Part 1 or 2.

(3) Where a person has power under sub-paragraph (1) or (2) to seize anything, he 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 shall leave on the premises from which the thing was seized a statement giving particulars of what he has seized and stating that he has seized it.

Powers: supplementary

6 (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.

7 (1) A person's right to exercise a power under this Schedule is subject to his producing evidence of his entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—

(a) prepare a written report of the inspection or search, and

(b) if requested to do so by the appropriate person, give him a copy of the report.

(3) 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 (as defined in section 41);

(b) in relation to any other premises, the occupier.

Enforcement

8 (1) A person commits an offence if—

(a) he fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 6(3), or

(b) he intentionally obstructs the exercise of any right under this Schedule.

(2) A person guilty of an offence under this paragraph is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Interpretation

9 In this Schedule, "duly authorised person", in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision.

SCHEDULE 6

Section 56

CONSEQUENTIAL AMENDMENTS

Wills Act 1837 (c. 26)

1 In section 1 of the Wills Act 1837, in the definition of "will", after "child," there is inserted "and also to an appointment by will of a representative under section 4 of the Human Tissue Act 2004,".

Anatomy Act 1984 (c. 14)

2 In section 4 of the Anatomy Act 1984 (lawful examinations), in subsection (4) (which is expressed to be subject to subsections (5) to (8)), for "(5)" there is substituted "(6)".

Coroners Act 1988 (c. 13)

3 (1) The Coroners Act 1988 is amended as follows.

(2) In section 19 (post-mortem examination without inquest), after subsection (1) (which confers power to direct a person to make a post-mortem examination) there is inserted—

"(1A) 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 16(1) of the Human Tissue Act 2004 (under which a person may make a post-mortem examination only under the authority of a licence under that Act)."

(3) In section 21 (which confers powers to direct a person to make a post-mortem examination in connection with an inquest), after subsection (4) there is inserted—

"(4A) No direction under 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 16(1) of the Human Tissue Act 2004 (under which a person may make a post-mortem examination only under the authority of a licence under that Act)."

Human Organ Transplants Act 1989 (c. 31)

4 In section 1(1)(a) of the Human Organ Transplants Act 1989, for "Great Britain" there is substituted "Scotland".

Criminal Justice and Police Act 2001 (c. 16)

5 (1) Part 2 of the Criminal Justice and Police Act 2001 (powers of seizure) is amended as follows.

(2) In section 57 (retention of seized items), in subsection (1) (provisions in relation to which the section has effect), at the end there is inserted—

"(q) paragraph 5(4) of Schedule 5 to the Human Tissue Act 2004."

(3) In section 66 (interpretation of Part 2), in subsection (4) (references to a search to include references to activities authorised by virtue of specified powers), at the end there is inserted—

"(n) paragraph 2 of Schedule 5 to the Human Tissue Act 2004 (entry and inspection of licensed premises)."

(4) In Schedule 1 (powers of seizure), in Part 1 (powers to which section 50 of the Act applies), after paragraph 73D there is inserted—

"Human Tissue Act 2004 (c. 00)

73E 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 5 to the Human Tissue Act 2004."

Enterprise Act 2002 (c. 40)

6 (1) Paragraph 3(1)(b), (2) and (3) of Schedule 2 shall be taken to be within the definition of "provision" in section 268 of the Enterprise Act 2002 (c. 40)

(power to remove bankruptcy disqualifications under pre-8th November 2002 provisions or extend them to, or replace them with disqualifications of, persons subject to bankruptcy restrictions regimes).

(2) In its application by virtue of sub-paragraph (1), section 268 of the Enterprise Act 2002 (c. 40) shall have effect with the following modifications—

(a) subsections (5)(d), (6) to (8) and (15) (power to make application of disqualification provision subject to person's discretion) are omitted, and

(b) for subsection (13) (order under section to be made by statutory instrument after parliamentary approval of a draft) there is substituted—

"(13) An order under this section—

(a) must be made by statutory instrument, and

(b) shall be subject to annulment in pursuance of a resolution of either House of Parliament."

Asylum and Immigration (Treatment of Claimants, etc.) Act 2004

7 In section 4 of the Asylum and Immigration (Treatment of Claimants, etc.) Act 2004 (trafficking people for exploitation), in subsection (4)(b), for "the Human Organ Transplants (Northern Ireland) Order 1989 (S.I. 1989 / 2408 (N.I. 21))" there is substituted "under section 32 or 33 of the Human Tissue Act 2004".

SCHEDULE 7

Section 57

REPEALS AND REVOCATIONS

PART 1

REPEALS

Short title and chapter	*Extent of repeal*
Human Tissue Act 1961 (c. 54)	The whole Act.
Human Tissue Act (Northern Ireland) 1962 (c. 19 (N.I.))	The whole Act.
Anatomy Act 1984 (c. 14)	The whole Act.
Corneal Tissue Act 1986 (c. 18)	The whole Act.
Human Organ Transplants Act 1989 (c. 31)	The whole Act.
National Health Service and Community Care Act 1990 (c. 19)	In Schedule 9, paragraph 7.
Human Fertilisation and Embryology Act 1990 (c. 37)	In Schedule 4, paragraphs 8 and 9.
Health Authorities Act 1995 (c. 17)	In Schedule 1, paragraph 92.

PART 2

REVOCATIONS

Title	*Extent of revocation*
Corneal Tissue (Northern Ireland) Order 1988 (S.I. 1988/1844 (N.I. 14))	The whole Order.
Human Organ Transplants (Northern Ireland) Order 1989 (S.I. 1989/2408 (N.I. 21))	The whole Order.
Health and Personal Social Services (Northern Ireland) Order 1991 (S.I. 1991/194 (N.I. 1))	In Part II of Schedule 5, the entry relating to the Human Tissue Act (Northern Ireland) 1962.
Anatomy (Northern Ireland) Order 1992 (S.I. 1992/1718 (N.I. 11))	The whole Order.

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