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*Number 5 of 2024*

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**Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and  
Public Display) Act 2024**

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**HUMAN TISSUE (TRANSPLANTATION, POST-MORTEM, ANATOMICAL  
EXAMINATION AND PUBLIC DISPLAY) ACT 2024**

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ACTS REFERRED TO

Anatomy Act 1832 (2 & 3 Will., c.75)  
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Children and Family Relationships Act 2015 (No. 9)  
Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010 (No. 24)  
Civil Registration Act 2004 (No. 3)  
Companies Act 2014 (No. 38)  
Coroners Act 1962 (No. 9)  
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Data Protection Act 2018 (No. 7)  
Guardianship of Infants Act 1964 (No. 7)  
Health Act 2004 (No. 42)  
Health Act 2007 (No. 23)  
Health and Social Care Professionals Act 2005 (No. 27)  
Health Identifiers Act 2014 (No. 15)  
Judicial Separation and Family Law Reform Act 1989 (No. 6)  
Medical Practitioners Act 2007 (No. 25)  
Nurses and Midwives Act 2011 (No. 41)  
Petty Sessions (Ireland) Act 1851 (14 & 15 Vict., c.93)  
Social Welfare Consolidation Act 2005 (No. 26)





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*Number 5 of 2024*

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**HUMAN TISSUE (TRANSPLANTATION, POST-MORTEM, ANATOMICAL EXAMINATION AND PUBLIC DISPLAY) ACT 2024**

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An Act to provide for the removal, donation and use of organs and tissues and cells from deceased and living persons for the purposes of transplantation; to make provision for the establishment and maintenance of a register in respect of certain organs whereby persons who do not wish to donate certain organs after death may register objection to donation of such organs; to provide for the establishment of a panel of persons to oversee certain proposed donations in respect of certain persons; to make provision for the carrying out of post-mortem examinations in hospitals and other non-hospital settings and the regulation of such activity; to make provision for the donation by living persons of their bodies after death for the purposes of anatomical examination or public display; to provide for the establishment of a licensing system in respect of persons undertaking anatomical examinations or public display activities; to provide that consent is pre-requisite for all procedures involving human organs and tissues and cells and for procedures relating to carrying out of anatomical examinations or public display activities; to make provision for the protection of the bodily integrity of persons before and after death; to provide for the monitoring and enforcement of compliance with these and other matters; and, for these and other purposes, to amend the Assisted Decision-Making (Capacity) Act 2015, the Medical Practitioners Act 2007, the Coroners Act 1962, the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006, the European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012 and certain other enactments; to repeal the Anatomy Act 1832; and to provide for related matters. [28th February, 2024]

**Be it enacted by the Oireachtas as follows:**

PART 1

PRELIMINARY AND GENERAL

**Short title, commencement and collective citation**

1. (1) This Act may be cited as the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024.

- (2) Subject to *subsection (3)*, this Act shall come into operation on such day or days as the Minister may appoint by order or orders either generally or with reference to any particular purpose or provision and different days may be so appointed for different purposes or different provisions.
- (3) *Sections 39(2)(b)*, and *58* and *60* shall come into operation on such day or days as the Minister may, after consultation with the Minister for Justice, appoint by order or orders either generally or with reference to any particular purpose or provision and different days may be so appointed for different purposes or different provisions.
- (4) The Coroners Acts 1962 to 2024 and *sections 58* and *60* may be cited together as the Coroners Acts 1962 to 2024.

## Interpretation

### 2. In this Act—

“Act of 1962” means the Coroners Act 1962;

“Act of 2007” means the Medical Practitioners Act 2007;

“Act of 2015” means the Assisted Decision-Making (Capacity) Act 2015;

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

“anatomical specimen” means the body of a deceased person, including separated parts of such a body, to be used for the purpose of anatomical examination or public display activities;

“appropriate consent” has the meaning assigned to it by *section 10*;

“Authority”, other than in *Part 3*, means the Health Products Regulatory Authority;

“body” means the human body;

“capacity” means, in relation to a person, his or her decision-making capacity and shall be construed in accordance with section 3 of the Act of 2015;

“cells” means individual human cells or a collection of human cells when not bound by any form of connective tissue;

“child”, other than in *section 7*, means a person who has not attained 18 years of age;

“civil partner” has the same meaning as it has in the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010;

“cohabitant” means one of two adults (whether of the same or opposite sex) who live together as a couple in an intimate and committed relationship and who are not married to each other or civil partners of each other;

“consent” means the giving of a permission or an agreement, that is voluntarily and freely given or made, for the use of human cells, organs and tissues—

- (a) for the purpose of transplantation activities, post-mortem examinations, anatomical examination or public display, as the case may be, and

- (b) in respect of which purpose, the person giving consent has received information sufficient to allow that person to understand the nature, risks, and benefits of the proposed purpose;

“coroner” has the same meaning as it has in section 2(1) of the Act of 1962;

“deemed consent” shall be construed in accordance with *section 18*;

“designated family member” has the meaning assigned to it by *section 7*;

“disposal”, in relation to the body or part of a body of a deceased person, means lawful disposal, either on land or at sea, by burial, cremation, scattering of the ashes of the remains of the body or other appropriate means;

“donation” means—

- (a) in relation to transplantation activities, the donation of human organs for transplantation or human tissues and cells for human application, or
- (b) in relation to anatomical examination or public display, the donation of the body;

“donor” means—

- (a) in relation to the donation of organs, a person who donates human organs whether or not that donation takes place during the lifetime or after the death of the person,
- (b) in relation to the donation of tissues and cells, a person who donates tissues and cells, whether or not that donation takes place during the lifetime or after the death of the person, or
- (c) in relation to the donation of a person’s body for the purposes of anatomical examination or for public display, the person who so donates his or her body for that purpose;

“Executive” means the Health Service Executive;

“guidelines” means guidelines issued by the Minister under *section 6*;

“healthcare professional” means—

- (a) a registered medical practitioner,
- (b) a registered nurse or registered midwife within the meaning of section 2(1) of the Nurses and Midwives Act 2011, or
- (c) a member of one or more of the following designated professions within the meaning of section 3 of the Health and Social Care Professionals Act 2005, namely:
  - (i) medical scientist;
  - (ii) psychologist;
  - (iii) social care worker;
  - (iv) social worker;

- (v) such other designated profession within the meaning of the said section as the Minister considers appropriate and may prescribe by regulations under *section 3*;

“human application” means the use of tissues or cells on or in a human recipient and extracorporeal applications;

“licensed institution” has the meaning assigned to it by *section 61*;

“living donation” means a donation of organs, tissues and cells by a living person;

“medical speciality” means a medical speciality recognised by the Medical Council under section 89 of the Act of 2007;

“Minister” means the Minister for Health;

“non-coronial post-mortem examination” has the meaning assigned to it by *section 38*;

“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 and a part of an organ shall be 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;

“*Part 5* licence holder” has the meaning assigned to it by *section 84*;

“parent” means—

- (a) in relation to a child, subject to *paragraph (b)*, the father or mother (within the meaning of section 2 of the Guardianship of Infants Act 1964) of the child,
- (b) in relation to a child who is a donor-conceived child, the parent or parents of that child under section 5 of the Children and Family Relationships Act 2015, or
- (c) in relation to a child where one parent has the sole custody, charge or care of the child, that parent;

“pathologist” means a registered medical practitioner who is qualified by virtue of his or her training and expertise to perform post-mortem examinations;

“post-mortem activities” has the meaning assigned to it by *section 42*;

“post-mortem consent” means the consent of a person to post-mortem activities in accordance with *section 47, 48, 49 or 50*;

“prescribed” means prescribed by regulations made by the Minister;

“preservation” means—

- (a) in relation to an organ, the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of the organ from procurement to transplantation, and
- (b) in relation to tissues or cells, the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of the tissues or cells;

“Register” has the meaning assigned to it by *section 32*;

“register of medical practitioners” has the same meaning as it has in the Act of 2007;

“registered medical practitioner” means a person who is a registered medical practitioner within the meaning of section 2 of the Act of 2007;

“Regulations of 2006” means the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006);

“Regulations of 2012” means the European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012);

“Specialist Division” has the same meaning as it has in the Act of 2007;

“tissue” means all constituent parts of the human body formed by cells;

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

“writing” includes electronic communication, voice and video recording and speech recognition technologies.

### **Regulations**

3. (1) The Minister may by regulations provide for any matter referred to in this Act as prescribed or to be prescribed.
- (2) Without prejudice to any provision of this Act, regulations under this section may contain such incidental, supplementary and consequential provisions as appear to the Minister to be necessary or expedient for the purposes of the regulations.
- (3) Every regulation made by the Minister under this Act shall be laid before each House of the Oireachtas as soon as may be after it is made and, if a resolution annulling the regulation is passed by either such House within the next 21 days on which that House sits after the regulation is laid before it, the regulation shall be annulled accordingly, but without prejudice to the validity of anything previously done thereunder.

### **Expenses**

4. The expenses incurred by the Minister in the administration of this Act shall, to such extent as may be sanctioned by the Minister for Public Expenditure, National Development Plan Delivery and Reform, be paid out of moneys provided by the Oireachtas.

### **Service of documents**

5. (1) A notice or other document that is required to be served on or given to a person under this Act shall be addressed to the person concerned by name, and may be so served on or given to the person in one of the following ways:

- (a) by delivering it to the person;
  - (b) by leaving it at the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, at that address;
  - (c) by sending it by post in a prepaid registered letter to the address at which the person ordinarily resides or, in a case in which an address for service has been furnished, to that address;
  - (d) by sending it by means of electronic mail to the email address of the person in a case where the person giving the notice reasonably believes that the email address is being used by the first-mentioned person.
- (2) For the purpose of this section, a company formed and registered under the Companies Act 2014 or an existing company within the meaning of that Act shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body of persons shall be deemed to be ordinarily resident at its principal office or place of business.

### **Guidelines**

6. (1) The Minister may, after consultation with—
- (a) in the case of *Part 2*, that part of the Executive known as the office for Organ Donation and Transplant Ireland, and the Authority,
  - (b) in the case of *Part 3*, the Health Information and Quality Authority,
  - (c) in the case of *Parts 4* and *5*, the Medical Council, and
  - (d) such other persons as he or she considers appropriate,
- prepare and issue guidelines for the purpose of providing practical guidance as regards the operation of, and compliance with, this Act and any regulations made under it.
- (2) The Minister shall publish guidelines prepared and issued under this section.

### **Designated family member in relation to relevant person**

7. (1) (a) This section shall apply to—
- (i) the seeking and obtaining of appropriate consent or where deemed consent applies, seeking confirmation that there is no objection to a proposed transplantation of organs of a relevant person in accordance with *Part 2*,
  - (ii) the seeking and obtaining of appropriate consent in relation to a proposed removal of tissue and cells from a relevant person in accordance with *Part 2*, and
  - (iii) the seeking and obtaining of post-mortem consent in relation to any proposed post-mortem activity in respect of a relevant person in accordance with *Part 3*.

- (b) Subject to this section, when a registered medical practitioner or suitably qualified person under the direction of a registered medical practitioner is—
- (i) seeking and obtaining appropriate consent or, where deemed consent applies, seeking confirmation that there is no objection to a proposed transplantation of organs of a relevant person in accordance with *Part 2*,
  - (ii) seeking and obtaining appropriate consent in relation to a proposed removal of tissues and cells from a relevant person in accordance with *Part 2*, or
  - (iii) seeking and obtaining of post-mortem consent in relation to any proposed post-mortem activity in respect of a relevant person in accordance with *Part 3*,
- he or she shall seek such consent or confirmation from a designated family member.
- (2) In this Act, a “designated family member” means a person, who is, or was immediately before the death of the relevant person—
- (a) a spouse or civil partner of the relevant person,
  - (b) a cohabitant of the relevant person,
  - (c) a child of the relevant person,
  - (d) a parent of the relevant person or a person who was a guardian of the relevant person before that relevant person attained 18 years,
  - (e) a brother or sister (whether of the whole or half blood) of the relevant person,
  - (f) a grandparent of the relevant person,
  - (g) a grandchild of the relevant person,
  - (h) an uncle or aunt (whether of the whole or half blood) of the relevant person,
  - (i) a niece or nephew of the relevant person, or
  - (j) a close friend of the relevant person who can demonstrate to the satisfaction of the person seeking consent or confirmation, as the case may be, that he or she can determine and accurately convey the wishes of the relevant person concerned.
- (3) Where in relation to a relevant person, a person referred to in *subsection (2)* is a person—
- (a) to whom a deed of separation or a decree of judicial separation is granted in relation to the relevant person,
  - (b) who has entered into a written agreement to separate with the relevant person,
  - (c) who has separated and ceased to cohabit with the relevant person for a continuous period of at least 12 months,
  - (d) who does not have the capacity to consent, or

- (e) who immediately before the death of the relevant person, had not yet attained the age of 18 years (other than where he or she is the parent of that relevant person), that person shall be disregarded for the purpose of *subsection (1)*.
- (4) Appropriate consent, including post-mortem consent, as appropriate, or, in the case of deemed consent, confirmation that there is no objection to deemed consent may be obtained from any designated family member with whom the registered medical practitioner has had real and substantial contact in relation to the care and treatment of the relevant person.
- (5) Where *subsection (4)* does not apply, appropriate consent, including post-mortem consent, as appropriate, or confirmation that there is no objection to deemed consent shall be obtained from a person whose relationship to the relevant person is accorded the highest ranking in accordance with *subsection (2)*.
- (6) Where more than one person falls within a paragraph in *subsection (2)*—
- (a) each person within that paragraph shall be ranked equally, and
  - (b) consent or confirmation that there is no objection to deemed consent may be obtained from any of the persons referred to within that paragraph.
- (7) In a case where persons of equal rank referred to in *subsection (6)(a)* are not in agreement and are unable to reach agreement in relation to consent or in the case of deemed consent confirm that there is no objection, the registered medical practitioner or, a suitably qualified person on behalf of the registered medical practitioner who is seeking such consent or confirmation in accordance with *subsection (1)* shall ask the persons concerned to reach a consensus agreement.
- (8) Where there is no appropriate consent, including post-mortem consent, as appropriate, or, in the case of deemed consent, no confirmation of no objection to deemed consent (by way of consensus reached under *subsection (7)* or otherwise), as the case may be, the proposed transplantation or non-coronial post-mortem examination concerned shall not, subject to *section 51*, proceed.
- (9) For the purposes of *subsection (1)*, a person who is not otherwise to be disregarded under *subsection (3)*, shall not be included as a designated person under *subsection (2)* if—
- (a) the person does not wish to consider whether or not he or she objects or consents,
  - (b) the person is unable to make a decision whether or not to object or consent,
  - (c) the person is unable to confirm that there is no objection to deemed consent,
  - (d) having regard to the proposed transplantation or non-coronial post-mortem examination in relation to which consent is sought, it is not reasonably practicable to communicate with the person in the time available if consent in relation to the transplantation or examination is to be acted on, or
  - (e) the relationship between the person and the relevant person cannot be confirmed for the purpose of this section.



- (10) Where a designated family member is considering whether to provide appropriate consent, including post-mortem consent, as appropriate, consent or, in the case of deemed consent, confirmation of no objection, the family member shall consider and give substantial weight as to whether or not he or she believes that the relevant person, the subject of the request, would have had an objection to such donation, removal or non-coronial post-mortem examination.
- (11) Without prejudice to the generality of *section 6*, the Minister shall issue guidelines in relation to the operation of this section, which guidelines shall include and make provision for the standard of contact appropriate to establish real and substantial contact for the purposes of *subsection (4)*.
- (12) In this section—
- “decree of judicial separation” means—
- (a) a decree under section 3 of the Judicial Separation and Family Law Reform Act 1989, or
  - (b) a decree or order (howsoever described) of like effect to the decree referred to in *paragraph (a)* granted under the law of a place other than the State and recognised under the law of the State;
- “relevant person”, means the deceased person in relation to whom—
- (a) appropriate consent for proposed transplantation activities or confirmation that there is no objection to deemed consent under *Part 2* is sought, or
  - (b) post-mortem consent for a non-coronial post-mortem examination in accordance with *Part 3* is sought.

**Provisions for storage, handling, transportation, and respectful disposal or return of bodies, anatomical specimens, organs or tissue**

- 8.** (1) Subject to this section, the storage, handling, transportation, disposal and return of an organ, tissue, body, body parts or an anatomical specimen may be undertaken where such storage, handling, transportation, disposal or return—
- (a) is undertaken in connection with any act done in accordance with *Part 2, 3, 4 or 5* of this Act, as the case may be, and
  - (b) has been subject to the consent as appropriate under the Part to which the organ, tissue, body, body parts or anatomical specimen relates.
- (2) Any storage, handling, transportation, disposal or return of an organ, tissue, body, body parts or anatomical specimen undertaken in relation to a deceased person shall have due regard to the dignity, bodily integrity and privacy of the deceased person.
- (3) Storage, handling, transportation, disposal or return of an organ, tissue, body, body part or anatomical specimen undertaken shall be recorded in writing by the hospital, licensed institution or *Part 5* licence holder, as the case may be so as to ensure traceability.

- (4) A reference in this Act to the storage, handling, transportation, disposal and return of an organ, tissue, body, body part or anatomical specimen shall not include a reference to—
- (a) any activity which is related to arrangements regarding a funeral, burial or cremation of a body,
  - (b) blood and blood components intended for transfusion in accordance with the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 (S.I. No. 360 of 2005), or
  - (c) storage, handling, transportation and return, where applicable, of—
    - (i) organs for transplantation, in accordance with the Regulations of 2012, and
    - (ii) tissues and cells intended for human application, in accordance with the Regulations of 2006.
- (5) Nothing in this section shall operate to affect the law in relation to the duties of executors or administrators of a deceased person’s estate in so far as such duties concern the disposal of the body of the deceased person.
- (6) A person who is in lawful possession of an anatomical specimen under *Part 5* or organs or tissues of a deceased person shall be responsible for the disposal or return of the anatomical specimen, or organs or tissues or their return to the designated family member, subject to the wishes of the designated family member.

## PART 2

### TRANSPLANTATION

#### CHAPTER 1

##### *Preliminary and general (Part 2)*

### **Interpretation and application**

**9.** (1) In this Part—

“blood” means whole human blood collected from a donor and processed for transfusion or further manufacturing;

“blood component” means a therapeutic constituent of blood, namely red cells, white cells, platelets and plasma, that can be prepared by various methods;

“broker” means a person or entity that facilitates or offers to facilitate the transaction of a potential organ donation for financial compensation or other non-financial inducements;

“domino organ transplantation operation” means a transplantation operation performed on a living person by a registered medical practitioner which is designed to safeguard or promote the physical health of the person by transplanting an organ into

that person and, by so doing, necessitating the removal of an organ from that person which, in turn, is intended to be used for transplantation in respect of another living person;

“identified recipient” means in relation to a proposed transplantation activity, the person identified by the transplantation centre as being the person who will benefit from the proposed transplantation activity and who is generally known to the donor;

“importing tissue establishment” means a tissue bank or a unit of a hospital or another body established within the State which is a party to a contractual agreement with a third country supplier for the import into the European Union of tissues and cells coming from a third country intended for human application;

“non-directed altruistic donation” means the donation from an adult living donor who wishes to donate an organ for transplantation to a person neither named nor specified by that donor;

“non-directed altruistic donor” means an adult living donor who wishes to donate an organ for transplantation to a person neither named nor otherwise specified by that donor;

“organ donor” means a person who donates one or several organs, whether the donation of that organ or those several organs occurs during the lifetime or after the death of the donor;

“Panel” has the meaning assigned to it by *section 27*;

“processing” means all operations involved in the preparation, manipulation, preservation, and packaging of tissues and cells intended for human applications;

“procurement” means—

- (a) in relation to an organ, a process by which the donated organ becomes available, and
- (b) in relation to tissues and cells, a process by which tissues and cells are made available;

“procurement organisation” means—

- (a) in relation to the procurement of human organs, 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 Authority in accordance with the Regulations of 2012, and
- (b) in relation to the procurement of tissues and cells, a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of tissues and cells, and is authorised to do so by the Authority in accordance with the Regulations of 2006;

“psychiatrist” means a medical practitioner who is for the time being registered in the Specialist Division of the register of medical practitioners under the medical specialty of “Psychiatry” or under the medical specialty of “Child and Adolescent Psychiatry”;

“regenerative tissue and cells” means tissue and cells which have regenerative properties and can be placed in the body of a living person, if the original tissue and cells in the body of the living person are injured or removed, in order to replace the original tissue and cells;

“Register” shall be construed in accordance with *section 32*;

“relevant organ” means a liver, lung, pancreas, heart or kidney;

“relevant professional” means—

(a) in relation to organ transplantation—

(i) a registered medical practitioner, or

(ii) a suitably qualified person acting on behalf of the registered medical practitioner,

and

(b) in relation to tissue and cells for human application—

(i) a registered medical practitioner,

(ii) a suitably qualified person acting on behalf of the registered medical practitioner, or

(iii) a person referred to in Regulation 9(4)(a) of the Regulations of 2006;

“specified person” has the meaning assigned to it by *section 25(4)*;

“storage” means, in relation to tissues and cells, maintaining the tissues and cells under appropriate controlled conditions until distribution;

“sufficient information” means, in relation to the seeking of consent by a relevant professional from a person, or the designated family member, or in the case of deemed consent, confirmation from the designated family member that there is no objection to transplantation activities—

(a) clear information sufficient to enable the person concerned to understand the transplantation activities that are proposed to be carried out including information regarding the following:

(i) the purpose and nature of the procurement, its consequences and risks;

(ii) any analytical tests that may be performed;

(iii) the recording and protection of donor data;

(iv) medical confidentiality;

(v) the therapeutic purpose and potential benefits of the proposed activities to which the consent relates;

(vi) the applicable safeguards intended to protect the donor (including confidentiality),

and

- (b) any information that it would be reasonable, on the request of the donor or designated family member, for the relevant professional to provide to that person in relation to the transplantation activities before or after such activities take place;

“third country supplier” means a tissue establishment or another body, established in a third country, which is responsible for the export to the European Union of tissues and cells it supplies to an importing tissue establishment, which supplier may also carry out one or more of the activities, which take place outside of the European Union, of donation, procurement, testing, processing, preservation, storage or distribution of tissues and cells imported into the European Union;

“tissue donor” means a human source, whether living or deceased, of human tissue of cells;

“tissue establishment” means a tissue bank or a unit of a hospital or another body where activities of donation, procurement, testing, processing, preservation, storage or distribution of human tissues and cells are undertaken;

“tissue recipient” means a person who receives tissues and cells for transplantation into his or her own body tissue from either—

- (a) his or her own body, or
- (b) the body of another person;

“transplantation activities” shall be construed in accordance with *section 11*;

“transplantation centre” means a healthcare establishment, a team or a unit of a hospital or any other body which is authorised under the Regulations of 2012 to undertake the transplantation of organs in accordance with those Regulations.

(2) References in this Part to—

- (a) “removal”, in relation to removal of organs from a body for the purposes of transplantation or removal of tissues and cells from a body for the purposes of human application, does not include—
  - (i) the removal of blood or blood components from a body, or
  - (ii) the removal of tissues and cells to be used as an autologous graft within the same surgical procedure,

and

- (b) “tissues and cells” does not include—
  - (i) an organ, or
  - (ii) any reproductive cells, within the meaning of the Regulations of 2006, taken for the purposes of the provision of assisted human reproduction in accordance with those Regulations.

**Deemed consent and appropriate consent – general provisions**

- 10.** (1) For the purposes of this Part, where deemed consent applies in respect of a deceased adult in accordance with *section 18* and there is no objection to transplantation activities by the designated family member—
- (a) the designated family member shall confirm in writing, in the presence of a witness who shall attest the designated family member’s confirmation, that he or she has no objection to such transplantation activities, or
  - (b) in a case where the family member concerned cannot provide confirmation in writing for any reason, that confirmation may be given orally by the person in the presence of two witnesses each of whom shall attest that the person has no objection.
- (2) (a) For the purposes of this Part, “appropriate consent” means consent provided without duress or coercion—
- (i) in relation to a deceased adult who is not registered on the Register and in respect of whom deemed consent does not apply, by the designated family member in accordance with *section 19*,
  - (ii) in relation to a deceased child, by a parent or guardian in accordance with *section 21*,
  - (iii) in relation to the donation of an organ by a living adult donor or a non-directed altruistic donor, by the donor and, in the case of a non-directed altruistic donor, with the approval of the Panel in accordance with *section 29*,
  - (iv) in relation to the donation of tissues and cells by a living adult donor, by the donor,
  - (v) in relation to the donation of regenerative tissues and cells by a living child, by a parent or guardian, with the approval of a Panel in accordance with *section 31*,
  - (vi) in relation to the donation of regenerative tissues and cells by a living adult who lacks capacity, by the specified person concerned in accordance with *section 25*, with the approval of the Panel in accordance with *section 30*,
  - (vii) in relation to a case to which *section 25(2)* applies, by the specified person concerned, or
  - (viii) in relation to a case to which *section 26(2)* applies, by a parent or guardian of the child.
- (b) For the purposes of this Part—
- (i) appropriate consent shall be in writing and shall be signed by the person giving the consent in the presence of a witness who shall attest the person’s signature, or

- (ii) in a case where the person cannot provide appropriate consent in writing that consent may be given orally by the person in the presence of two witnesses each of whom shall attest that the person gave consent.
- (3) A copy of a confirmation referred to in *subsection (1)* or a copy of an appropriate consent referred to in *subparagraphs (i) to (viii) of subsection (2)(a)* shall be—
  - (a) retained with the medical records of the donor for a period of 30 years, and
  - (b) offered to the person providing confirmation or consent and, on his or her request, shall be given to that person.
- (4) Prior to any importation of an organ into the State for the purpose of transplantation activities, a transplantation centre shall satisfy itself that—
  - (a) the consent required for such transplantation activities has been obtained by the appropriate person in the country of origin where procurement of the organ took place, and
  - (b) the procurement of the organ meets the legal requirements of the country of origin in relation to the transplantation activities concerned.
- (5) Prior to any importation of any tissues and cells into the State for the purpose of transplantation activities, a tissue establishment or an importing tissue establishment shall satisfy itself that—
  - (a) the consent required for such transplantation activities has been obtained by the appropriate person in the country of origin where procurement of the tissues and cells took place, and
  - (b) the procurement of the tissues and cells meets the legal requirements of the country of origin in relation to the transplantation activities concerned.
- (6) A person who contravenes—
  - (a) *subsection (3)*,
  - (b) *subsection (4)*, or
  - (c) *subsection (5)*,shall be guilty of an offence.
- (7) In this section, “country of origin” means the country from which the organ or tissues and cells, as the case may be, was or were procured before being imported into the State.

### **Transplantation activities**

- 11.** (1) A person shall not carry out a transplantation activity unless he or she is satisfied—
- (a) where deemed consent applies and there is no objection to transplantation activities by the designated family member, that the family member has provided

confirmation that he or she has no objection to such activities in accordance with *section 10(1)*, or

- (b) that the appropriate consent has been provided.
- (2) For the purposes of this Part, transplantation activities means any or all of the following:
- (a) the removal of an organ from the body of a living or deceased person for the purposes of transplantation;
  - (b) the removal of tissues and cells from the body of a living or deceased person for the purposes of human application;
  - (c) the use of any organs or tissues and cells removed from the body of a living or deceased person for the purposes of transplantation under *paragraph (a)* or human application under *paragraph (b)*.
- (3) A person who contravenes *subsection (1)* shall be guilty of an offence.

### **Principles governing organ and tissue and cell donation**

12. (1) Subject to *subsection (3)*, any donation of an organ or tissues and cells from a deceased or living donor shall be voluntary and unpaid and any financial compensation or other like reward given in respect of a donation of an organ or tissues and cells shall render any consent provided null and void.
- (2) A person shall not act as a broker or advertise the need for, or availability of, an organ or tissues and cells in respect of potential donation of such organ or tissues and cells for the purpose of offering or seeking any financial compensation or other non-financial inducements.
- (3) A living donor may, subject to any regulations under *subsection (4)*, receive financial compensation in relation to the donation of an organ or tissues and cells, provided such compensation is strictly limited to making good the reasonable expenses related to the donation.
- (4) The Minister may prescribe by regulations the conditions under which compensation may be granted in accordance with *subsection (3)*, and such conditions shall ensure that there is no financial incentive or benefit to the donor in relation to the donation of an organ or tissues and cells.
- (5) Notwithstanding the generality of *subsection (4)*, regulations under that subsection may specify an upper limit in respect of the total amount of compensation payable to a living donor, and an upper limit payable in respect of any of the matters specified in *paragraphs (a) to (e) of subsection (10)*.
- (6) Before making regulations under *subsection (4)*, the Minister shall consult such persons as he or she considers appropriate including all or any of the following:
- (a) the Executive;
  - (b) the Authority;



- (c) a transplantation centre;
  - (d) a tissue establishment;
  - (e) any relevant patient advocacy group.
- (7) Subject to *subsection (8)*, the procurement of any organ or tissues and cells by a procurement organisation, tissue establishment or importing tissue establishment shall be carried out on a non-profit basis.
- (8) Nothing in *subsection (7)* shall be construed as prohibiting a procurement organisation, a tissue establishment or importing tissue establishment from charging reasonable fees to cover the costs of procuring, retrieving, storing, testing or distributing human organs or tissues and cells.
- (9) A person who contravenes *subsection (2)* shall be guilty of an offence.
- (10) In this section, “reasonable expenses” means, in relation to a living donor, the amount required to compensate a donor for—
- (a) travel costs,
  - (b) accommodation costs,
  - (c) childcare costs,
  - (d) medical expenses (including the costs of medical certificates), and
  - (e) loss of income,
- reasonably incurred by him or her in relation to the provision of the organ or tissue and cells, as the case may be, calculated in accordance with regulations under *subsection (4)*.

### **Priority of organ donation**

13. Subject to the Coroners Acts 1962 to 2024, the procurement of a person’s organs for transplantation shall have priority in relation to any consent provided—
- (a) for a non-coronial post-mortem examination in accordance with *Part 3*,
  - (b) by a person to donate his or her body for anatomical examination in accordance with *Part 4*, or
  - (c) by a person to donate his or her body for public display in accordance with *Part 5*.

### **Removal of tissue sample to determine viability of transplantation**

14. Where it appears to a relevant professional removing, in accordance with the appropriate consent, (or, where deemed consent applies, in accordance with confirmation that there is no objection) an organ for transplantation or tissues and cells for human application from a deceased person, that it is necessary or expedient to remove and examine a tissue sample from any part of the donor’s body to determine the viability of the proposed

transplantation activities (having regard, in particular, to the safety of the recipient), the person carrying out the removal may remove and examine such tissue sample as he or she considers necessary or expedient for such purposes.

#### **Preservation for transplantation activities – deceased persons**

15. (1) Notwithstanding the generality of *section 11* and subject to *subsection (3)*, where an organ or tissues and cells, or both organs and tissues and cells, as the case may be, from a deceased person are, or may be, suitable for procurement for transplantation activities, a relevant professional may—
- (a) take such steps as are reasonably necessary for the purpose of maintaining such organs or tissues and cells for procurement for transplantation activities, and
  - (b) in relation to a designated family member—
    - (i) where deemed consent applies, seek confirmation that the designated family member has no objection to the procurement for transplantation activities on the deceased person, or
    - (ii) where deemed consent does not apply, seek appropriate consent from the designated family member to the procurement for transplantation activities on the deceased person in accordance with *section 10*,and the body of that deceased person may be maintained for that purpose.
- (2) The steps referred to in *paragraph (a)* of *subsection (1)* may be taken before, during or after the confirmation or consent referred to in *paragraph (b)* of that subsection has been obtained.
- (3) Where the designated family member objects to the procurement for transplantation activities on a deceased person, a relevant professional shall cease to take the steps referred to in *subsection (1)*.

#### **Certification for transplantation activities – deceased donor**

16. (1) This section shall apply only to a deceased donor from whom an organ is removed or tissues and cells are removed when he or she is no longer alive.
- (2) A person shall not remove an organ or tissues and cells from another person (in this section referred to as the “relevant donor”) for the purposes of transplantation activities unless—
- (a) following a medical examination by a registered medical practitioner, he or she is satisfied that the relevant donor is no longer alive, and
  - (b) the confirmation or appropriate consent under *section 10(1)* and (2) is in place.
- (3) In so far as it is clinically appropriate, a registered medical practitioner referred to in *subsection (2)* who certifies the death of the relevant donor shall not—
- (a) have a primary role in relation to the removal of an organ or tissues and cells from the relevant donor,

- (b) have a primary role in relation to transplantation activities in respect of the relevant donor or recipient, or
  - (c) have primary responsibility for the medical treatment of the potential recipients of the organ or tissues and cells the subject of the transplantation activities.
- (4) A person who knows, or has reason to believe, that an examination of a body is, or may be, required by a coroner in accordance with the Coroners Acts 1962 to 2024, shall not remove an organ or tissues and cells from that body for the purpose of transplantation activities (or authorise another person to remove an organ or tissues and cells for such purposes), unless and until the coroner has confirmed that examination of the body is not required to enable the coroner to perform his or her functions under those Acts.
- (5) A coroner may provide confirmation under *subsection (4)* orally and, where he or she does so, he or she shall also, as soon as practicable thereafter, provide such confirmation in writing including details of the date on which and time at which that he or she provided such confirmation.
- (6) A person who contravenes—
- (a) *subsection (2)*, or
  - (b) *subsection (4)*,
- shall be guilty of an offence.

### **Review of operation of Relevant Organ Donation Opt-Out Register**

17. (1) The Minister shall, not later than 3 years after the commencement of this section, carry out a review of the operation of the Relevant Organ Donation Opt-Out Register.
- (2) In carrying out a review under *subsection (1)*, the Minister may consult with such and so many persons as he or she considers appropriate.

## CHAPTER 2

### *Consent*

### **Deemed consent for donation of relevant organs and removal of relevant organs**

18. (1) Subject to *subsections (2) and (3)*, a person shall be deemed to consent to the donation, after his or her death, of his or her relevant organs (in this Act referred to as “deemed consent”) where he or she has not registered his or her objection to such organ donation on the Register in accordance with *section 33*.
- (2) *Subsection (1)* shall not apply—
- (a) to a person who has not been ordinarily resident in the State for a period of at least 12 months immediately before the date of his or her death,
  - (b) to a person who, for a significant period before his or her death, lacked the capacity to understand that his or her consent would be deemed to be such if he

or she did not register an objection to the donation of his or her organs on the Register,

- (c) to a person in respect of whom a designated family member cannot be identified or confirmed, or
  - (d) to a child.
- (3) Where a person has not registered his or her objection to the donation of his or her relevant organs in accordance with *section 33*, a registered medical practitioner who, after the person's death proposes to remove a relevant organ from that person for the purposes of transplantation shall satisfy himself or herself that the designated family member of the person has confirmed that he or she does not have any objection to the donation of the relevant organ.
- (4) A registered medical practitioner shall not remove a relevant organ from a person for the purposes of transplantation if he or she has not satisfied himself or herself in accordance with *subsection (3)*.
- (5) Without prejudice to the generality of this section when seeking to satisfy him or herself as to whether there is any objection to the donation of a relevant organ to be used for transplantation, a relevant professional shall, in accordance with any guidelines and, where appropriate in accordance with the Regulations of 2012—
- (a) subject to Regulation 24(7) of the Regulations of 2012, provide the designated family member with sufficient information, and
  - (b) inform the designated family member of the effect of *subsection (9)*.
- (6) Where a designated family member is approached to confirm that there is no objection to the donation of relevant organs for the purpose of transplantation, the family member shall consider and give substantial weight as to whether or not he or she believes that the relevant person, the subject of the request, would have had an objection to such a procedure.
- (7) Where a designated family member objects to the donation of a relevant organ, the relevant organ shall not be used for transplantation and the objection of the designated family member shall be recorded in writing by the relevant professional and retained with the deceased person's medical records for a period of 30 years.
- (8) Where the designated family member has confirmed that he or she has no objection to the removal and donation of a relevant organ, he or she shall provide confirmation that the relevant organ may be used for transplantation in accordance with *section 10(1)*.
- (9) A designated family member may, at any time up to the commencement of the process for removal of the relevant organ for transplantation, object to the donation but no objection can be made once the process for removal of such relevant organ has begun.

**Consent for organ donation given by designated family member where deemed consent does not apply**

19. (1) This section applies to the donation of any organ from a deceased person where deemed consent does not apply in accordance with *section 18*.
- (2) A registered medical practitioner shall not remove any organ from a deceased person for the purpose of transplantation without appropriate consent.
- (3) When seeking appropriate consent from the designated family member for the donation of an organ from a deceased person for the purpose of transplantation, a relevant professional shall, in accordance with the Regulations of 2012 and any guidelines—
- (a) subject to Regulation 24(7) of the Regulations of 2012, provide the designated family member with sufficient information, and
- (b) inform the designated family member of the effect of *subsection (5)*.
- (4) Consent given by a person under this section is given only for the purposes of transplantation.
- (5) A designated family member may, at any time up to the commencement of the process for removal, withdraw consent referred to in *subsection (2)*, but such consent cannot be withdrawn once the process of removal has begun.

**Consent for tissues and cells donation given by designated family member in respect of deceased adult donor**

20. (1) This section applies to the donation of any tissues and cells from a deceased adult donor.
- (2) A relevant professional shall not remove any tissues and cells from a deceased person for the purpose of human application without the appropriate consent.
- (3) When seeking appropriate consent from the designated family member for the donation of tissues and cells to be used for human application, a relevant professional shall, in accordance with the Regulations of 2006 and any guidelines—
- (a) subject to Regulation 18(6) of the Regulations of 2006, provide the designated family member with sufficient information, and
- (b) inform the designated family member of the effect of *subsection (4)*.
- (4) A designated family member may, at any time up to the commencement of the process for retrieval of the tissues and cells for human application, withdraw consent referred to in *subsection (2)* but any such consent cannot be withdrawn once the process of removal has begun.

**Consent by parent or guardian in respect of deceased child**

21. (1) A registered medical practitioner shall not remove any organ for the purpose of transplantation from the body of a deceased child without the appropriate consent.

- (2) When seeking consent from a parent or guardian under *subsection (1)*, a relevant professional shall, in accordance with the Regulations of 2012 and any guidelines—
  - (a) subject to Regulation 24(7) of the Regulations of 2012, provide the parent or guardian concerned with sufficient information, and
  - (b) inform the parent or guardian, as the case may be, of the effect of *subsection (7)*.
- (3) A relevant professional shall not remove any tissues and cells for the purposes of human application from the body of a deceased child without the appropriate consent.
- (4) When seeking consent from a parent or guardian under *subsection (3)*, a relevant professional shall, in accordance with the Regulations of 2006 and any guidelines—
  - (a) subject to Regulation 18(6) of the Regulations of 2006, provide the parent or guardian concerned with sufficient information, and
  - (b) inform the parent or guardian, as the case may be, of the effect of *subsection (7)*.
- (5)
  - (a) Where one of the parents or guardians of a deceased child has provided consent in accordance with *subsection (1)* or *(3)*, as the case may be, (“the first parent or guardian”) and the other parent or another guardian objects to the consent provided by the first parent or guardian prior to the proposed removal of any organ or tissues and cells for donation, the consent provided by the first parent or guardian shall have no effect and shall be deemed invalid and accordingly no removal under *subsection (1)* or *(3)*, as the case may be, shall be undertaken.
  - (b) Without prejudice to the power of the Minister under *section 6* to prepare and issue guidelines in relation to any matter provided for under this Act, the Minister shall prepare and issue guidelines under that section for the purposes of providing practical guidance regarding the operation of *paragraph (a)*.
- (6) A parent of a deceased child may, for the purposes of this section, consent to the removal of any organ or tissues and cells from the body of his or her deceased child, notwithstanding that the parent has not yet attained the age of 18 years.
- (7) A parent or guardian, as the case may be, of a deceased child may amend or withdraw his or her consent, in accordance with this section at any time up to the commencement of the process for the transplantation of the organ concerned or the retrieval of the tissue and cells concerned but no further amendment or withdrawal of consent can be made or may be made once the process for transplantation of the organ concerned or the retrieval of the tissue and cells concerned, as the case may be, has begun.

## CHAPTER 3

*Conditions in relation to donation***Conditions in relation to donation of organs by living adults**

22. (1) A registered medical practitioner shall not remove an organ from a living adult donor for the purposes of transplantation of the organ to an identified recipient unless the following conditions are met:
- (a) appropriate consent has been given by the donor in accordance with *section 10*;
  - (b) the removal of the organ for the purpose of transplantation is solely for the therapeutic benefit of the recipient and there is no other alternative therapeutic method of comparable effectiveness;
  - (c) subject to *section 12* and any regulations made under that section, the donor has not and will not receive any financial compensation or other non-financial inducements for donating his or her organ;
  - (d) the donation of the organ is otherwise in accordance with the Regulations of 2012 in so far as those Regulations relate to transplantation activities under this Part.
- (2) A transplantation centre shall, in accordance with any guidelines, when seeking consent from a person (in this section referred to as a “potential organ donor”) provide the potential organ donor with—
- (a) sufficient information,
  - (b) access to independent advice on such organ removal and donation, and
  - (c) inform the person of the matters referred to in *subsection (4)*.
- (3) Independent advice provided under *subsection (2)(b)* shall be provided by an appropriately trained healthcare professional who is not involved or connected with either the removal of the organ from the potential organ donor or the subsequent transplantation.
- (4) A potential organ donor may, at any time up to the induction of anaesthesia for the process of removal of the organ for donation, withdraw consent given under *subsection (1)* but any consent given under *subsection (1)* cannot be withdrawn once the process of removal has begun.

**Conditions in relation to donation of tissues and cells by living adults**

23. (1) A relevant professional shall not remove tissues and cells from a living adult donor for the purpose of human application unless the following conditions are met:
- (a) appropriate consent has been provided by the donor of the tissue in accordance with *section 10*;

- (b) the donation of such tissues and cells is solely for the therapeutic benefit of the tissue recipient and there is no other alternative therapeutic method of comparable effectiveness;
  - (c) subject to *section 12* and any regulations made under that section, the tissue donor has not and will not receive any financial compensation or other non-financial inducements for donating his or her tissue and cells;
  - (d) the removal of the tissue and cells is otherwise in accordance with the Regulations of 2006 in so far as those Regulations relate to human application activities under this Part.
- (2) A tissue establishment or procurement organisation shall ensure that a relevant professional provides the donor with—
- (a) subject to Regulation 18(6) of the Regulations of 2006, sufficient information,
  - (b) access to independent advice on such tissues and cells removal and donation, and
  - (c) information in respect of the matters referred to in *subsection (4)*.
- (3) Independent advice provided under *subsection (2)(b)* shall be provided by an appropriately trained healthcare professional who is not involved or connected with either the removal of the cells and tissues from the potential tissue donor and subsequent human application.
- (4) A potential tissue donor may withdraw or amend consent provided in accordance with *subsection (1)* at any time up to the beginning of the process for the removal of the tissues and cells from that donor but any consent given under *subsection (1)* cannot be withdrawn or amended once the removal process has begun.

**Conditions in relation to donation of organs by non-directed altruistic donors**

24. (1) A registered medical practitioner shall not remove an organ for the purposes of non-directed altruistic donation unless the following conditions are met:
- (a) appropriate consent has been provided by the non-directed altruistic donor in accordance with *section 10*;
  - (b) the removal of the organ for the purpose of transplantation is solely for the therapeutic benefit of the recipient and there is no other alternative therapeutic method of comparable effectiveness;
  - (c) subject to *section 12* and any regulations under that section, the donor has not and will not receive any financial compensation or other non-financial inducements for donating his or her organ;
  - (d) approval for the removal of the organ has been given by the Panel in accordance with *section 29*;
  - (e) the removal of the organ is otherwise in accordance with the Regulations of 2012, in so far as those Regulations relate to transplantation activities under this Part.



- (2) A transplantation centre shall, provide a person (in this section referred to as a “potential organ donor”) with—
  - (a) subject to Regulation 24(7) of the Regulations of 2012, sufficient information,
  - (b) access to independent advice on such organ removal and donation, and
  - (c) information on the effect of *subsection (4)*.
- (3) Independent advice provided under *subsection (2)(b)* shall be provided by an appropriately trained healthcare professional who is not involved in, or connected with, either the removal of the organ from the potential organ donor or any subsequent transplantation procedures.
- (4) A potential organ donor may, at any time up to the induction of anaesthesia for the process of removal of the organ for donation, withdraw consent given under *subsection (1)* but any consent given under *subsection (1)* cannot be withdrawn once the process of removal has begun.
- (5) A non-directed altruistic donor may not direct or specify that his or her organ shall, or shall not, be donated to a person of a particular class or classes of persons.

**Conditions in relation to donation of organs and tissues and cells by living adults who lack capacity**

- 25.** (1) Subject to *subsection (2)*, a registered medical practitioner shall not, for the purpose of transplantation remove an organ from a living adult who lacks capacity.
- (2) *Subsection (1)* shall not apply to the removal of an organ that is necessarily removed from a living adult who lacks capacity during a domino organ transplantation operation where appropriate consent has been given by the specified person concerned.
  - (3) A relevant professional shall not remove, for the purposes of donation, any regenerative tissues and cells from a living adult who lacks capacity unless—
    - (a) he or she has obtained appropriate consent in accordance with *section 10*, and
    - (b) approval for the removal has been given by the Panel in accordance with *section 30*.
  - (4) In this section—
 

“decision-making representative” has the same meaning as it has in section 2 of the Act of 2015;

“decision-making representation order” has the same meaning as it has in section 2 of the Act of 2015;

“specified person”, in relation to a living adult who lacks capacity, means any of the following:

- (a) a decision-making representative where the terms of the decision-making representation order made in that regard under section 38(2)(b) of the Act of 2015 confers functions on the representative concerned in respect of the matter;
- (b) in the case of a ward of court, the committee of the ward of court;
- (c) any other person duly appointed in that behalf by the High Court.

**Conditions in relation to donation of organs and tissues and cells by living children**

26. (1) Subject to *subsection (2)*, a registered medical practitioner shall not, for the purpose of transplantation, remove an organ from a living child.
- (2) *Subsection (1)* shall not apply to the removal of an organ that is necessarily removed from a living child during a domino organ transplantation operation where appropriate consent has been given by a parent or guardian of the child.
- (3) A relevant professional shall not remove regenerative tissues and cells from a living child for the purposes of donation unless the following conditions are met:
- (a) the person has obtained appropriate consent provided in accordance with *section 10* from at least one parent or guardian of the child;
  - (b) approval for the removal has been given by the Panel in accordance with *section 31*.

## CHAPTER 4

*Independent panel***Independent panel for certain cases of living donation of organs and tissue and cells**

27. (1) Subject to *section 28*, the Minister shall establish and maintain a panel of suitable persons (in this Part referred to as the “Panel”) for the purposes of considering applications for donations by living persons of organs and tissues and cells relating to—
- (a) the donation of an organ from a non-directed altruistic donor,
  - (b) the donation of regenerative tissues and cells from an adult who lacks capacity, and
  - (c) the donation of regenerative tissues and cells from a living child.
- (2) The members of the Panel shall be appointed on a part-time basis for such term, not exceeding 4 years, as the Minister may determine and a member may be reappointed by the Minister for an additional term.
- (3) A member of the Panel shall be entitled to be paid such fees or allowances for expenses as the Minister, with the consent of the Minister for Public Expenditure, National Development Plan Delivery and Reform, determines.

- (4) A member of the Panel may at any time resign by giving notice in writing to the Minister of his or her resignation.
- (5) A resignation under *subsection (4)* takes effect on the day on which the Minister receives the notice.
- (6) The Minister may at any time remove from office a member of the Panel if, in the opinion of the Minister—
  - (a) the member has become incapable through ill-health of effectively performing his or her functions,
  - (b) the member has committed stated misbehaviour, or
  - (c) the removal of the member appears to the Minister to be necessary for the effective performance by the Panel of its functions.
- (7) Subject to the provisions of this Act, the Panel shall be independent and impartial in the performance of its functions.
- (8) The Minister shall provide such support of an administrative nature to the Panel as the Minister considers necessary to enable the Panel to perform its functions.

### **Composition of Panel**

- 28.** (1) The Panel shall consist of 8 members, of which—
- (a) at least one shall be an ethicist,
  - (b) at least one shall be a practising barrister or practising solicitor,
  - (c) at least one shall be a registered medical practitioner, other than a psychiatrist, who has relevant expertise in organ transplantation,
  - (d) at least one shall be a psychiatrist, and
  - (e) at least 2 shall be patient advocates and, of those 2, at least one may be a donor patient advocate.
- (2) The Minister shall appoint a chairperson from the members of the Panel and he or she shall be a registered medical practitioner.
- (3) The quorum for the Panel, when considering an application under *section 29(1), 30(1) or 31(1)* shall be four, and any decision of the Panel shall be decided by a majority of votes and, in the case of an equality of votes, the chairperson shall have a second or casting vote.

### **Application to Panel for non-directed altruistic donation**

- 29.** (1) Where a non-directed altruistic donation is proposed in accordance with *section 24*, the transplantation centre which has clinical responsibility for the removal of the organ shall apply to the Panel for approval for such proposed donation.

- (2) An application under *subsection (1)* shall be made to the Panel in such form or manner as may be specified by the Panel.
- (3) On receipt of an application under *subsection (1)*, the Panel shall appoint a suitably qualified professional, who shall not be a member of the Panel, to prepare a report as to whether the conditions specified in *paragraphs (a) to (e)* of *section 24(1)* have been met for the purposes of such donation.
- (4) The person appointed under *subsection (3)* shall prepare a report in accordance with that subsection and furnish the report to the Panel not later than 15 days after his or her appointment.
- (5) The Panel shall take into account the report prepared in accordance with *subsection (3)* when making any decision regarding an application under *subsection (1)* which decision shall be made as soon as may be after receipt of the report.
- (6) The Panel, having taken account of the report prepared under *subsection (3)*, shall—
  - (a) approve an application under *subsection (1)* where it is satisfied that the conditions for non-directed altruistic donation specified in *paragraphs (a) to (e)* of *section 24(1)* have been met, or
  - (b) refuse an application under *subsection (1)* where it is not satisfied that the conditions for non-directed altruistic donation specified in *paragraphs (a) to (e)* of *section 24(1)* have been met.
- (7) The Panel shall give notice in writing of a decision to approve or refuse an application made under *subsection (1)* to—
  - (a) the donor of the transplantable organ or any person acting on his or her behalf, and
  - (b) the transplantation centre which made the application under *subsection (1)*.
- (8) A copy of the report provided in accordance with *subsection (3)*—
  - (a) shall be retained with the medical records of the person donating the organ for a period of not less than 30 years,
  - (b) shall be retained by the transplantation centre for a period of not less than 30 years, and
  - (c) shall be offered to the person donating the organ and shall, on his or her request, be given to that person.

**Application to Panel for donation of regenerative tissue and cells by living adults who lack capacity**

- 30.** (1) Where a donation of regenerative tissue and cells is proposed in accordance with *section 25(3)*, the tissue establishment or procurement organisation, as the case may be, with clinical responsibility for the removal of the regenerative tissue and cells shall apply to the Panel for approval for such proposed donation.

- (2) An application under *subsection (1)* shall be made to the Panel in such form and manner as may be specified by the Panel.
- (3) On receipt of an application under *subsection (1)*, the Panel shall appoint a suitably qualified professional, who shall not be a member of the panel, to prepare a report as to whether the appropriate consent has been provided for the purposes of such donation.
- (4) The person appointed under *subsection (3)* shall prepare a report in accordance with that subsection and furnish the report to the Panel not later than 15 days after his or her appointment.
- (5) The Panel shall take into account the report prepared in accordance with *subsection (3)* when making any decision regarding an application under *subsection (1)* which decision shall be made as soon as may be after receipt of the report.
- (6) The Panel may approve an application under *subsection (1)* where it is satisfied that—
  - (a) having taken account of the report prepared in accordance with *subsection (3)*, appropriate consent has been provided in accordance with *section 10*,
  - (b) the adult who lacks capacity, the subject of the application, does not object to the proposed donation,
  - (c) the proposed recipient is a parent, child or sibling of the donor and there is no other compatible donor with the capacity to consent available,
  - (d) there is no alternative therapeutic intervention of comparable effectiveness available,
  - (e) the donation of the regenerative tissue and cells by the donor has been clinically assessed by a registered medical practitioner as having the potential to be life-saving for the recipient, and
  - (f) the specified person and, where applicable, the proposed donor has been given sufficient information.
- (7) The Panel shall refuse an application under *subsection (1)* where it is not satisfied that the conditions specified in *subsection (6)* are met.
- (8) In considering an application under *subsection (1)*, the Panel shall have regard to—
  - (a) the report under *subsection (3)*, and
  - (b) the opinion of the proposed donor, the subject of the application.
- (9) The Panel shall give notice in writing of a decision to approve an application in accordance with *subsection (6)* or to refuse an application in accordance with *subsection (7)* to—
  - (a) the proposed donor the subject of the application, or any person acting on his or her behalf or the specified person concerned, as the case may be, and

- (b) the tissue establishment or procurement organisation which caused the matter to be referred to the Panel under *subsection (1)*.
- (10) A copy of the report provided in accordance with *subsection (3)*—
- (a) shall be retained by the tissue establishment or procurement organisation, which carried out the procedure, for a period of not less than 30 years—
    - (i) with the medical records of the person donating the regenerative tissue and cells, and
    - (ii) by the tissue establishment or procurement organisation which carried out the procedure,and
  - (b) shall be offered to the person providing consent and shall, on his or her request, be given to that person.

#### **Application to Panel for donation of regenerative tissue and cells by living child**

- 31.** (1) Where a donation of regenerative tissue and cells from a living child is proposed in accordance with *section 26(3)*, the tissue establishment or procurement organisation, as the case may be, with clinical responsibility for the removal of the regenerative tissue and cells shall, apply to the Panel for approval for such proposed donation.
- (2) An application under *subsection (1)* shall be made in such form and manner as may be specified by the Panel.
- (3) On receipt of an application under *subsection (1)*, the Panel shall appoint a suitably qualified professional, who shall not be a member of the Panel, to prepare a report as to whether appropriate consent has been provided for the purposes of such donation.
- (4) The person appointed under *subsection (3)* shall prepare a report in accordance with that subsection and furnish the report to the Panel not later than 15 days after his or her appointment.
- (5) The Panel shall take into account the report prepared in accordance with *subsection (3)* when making any decision regarding an application under *subsection (1)*.
- (6) The Panel may approve an application under *subsection (1)* where it is satisfied that—
- (a) having taken account of the report prepared in accordance with *subsection (3)*, appropriate consent has been provided in accordance with *section 10*,
  - (b) subject to *subsection (7)*, consent has been given to the proposed donation by at least one parent or guardian,
  - (c) the opinion of the child the subject of the application, having regard to his or her age, degree of maturity and decision-making competence in relation to making a decision in respect of the donation and that he or she does not object to the proposed donation,

- (d) the parent or guardian, or where applicable the child, the subject of the application has been given sufficient information,
  - (e) the proposed recipient is a parent (including a parent who has not yet attained 18 years), child or sibling of the donor and there is no other compatible donor with the capacity to consent available,
  - (f) there is no alternative therapeutic intervention of comparable effectiveness, and
  - (g) the donation of the regenerative tissue and cells by the donor has been clinically assessed by a registered medical practitioner as having the potential to be life-saving for the recipient.
- (7) Where a parent or guardian objects in writing to the consent given by the other parent or guardian, the consent given by the first-mentioned parent or guardian shall have no effect and shall be deemed invalid for the purposes of this section.
- (8) The Panel shall refuse an application under *subsection (1)* where it is not satisfied that the conditions specified in *subsection (6)* are met.
- (9) In considering an application under *subsection (1)*, the Panel shall have regard to—
- (a) the report under *subsection (3)*, and
  - (b) the views of the proposed donor, the subject of the application.
- (10) The Panel shall give notice in writing of a decision to approve an application under *subsection (6)* or refuse an application under *subsection (8)*, as the case may be, to—
- (a) the parent or guardian of the child the subject of the application, and
  - (b) the tissue establishment or procurement organisation, as the case may be, who caused the matter to be referred to the Panel under *subsection (1)*.
- (11) A copy of the report provided in accordance with *subsection (3)*—
- (a) shall be retained with the medical records of the child donating the regenerative tissue and cells, for a period of not less than 30 years, by the tissue establishment or procurement organisation, as the case may be, which carried out the procedure, and
  - (b) shall be offered to the person providing consent and shall, on his or her request, be given to that person.

## CHAPTER 5

### *Relevant Organ Donation Opt-Out Register*

#### **Relevant Organ Donation Opt-Out Register**

32. (1) The Executive shall, as soon as practicable after the commencement of this section, establish and maintain in such form as it considers appropriate, a register to be known as the Relevant Organ Donation Opt-Out Register (in this Part referred to as “the Register”).

- (2) The Executive shall make an entry in the Register of the details specified in *subsection (3) of section 33* in respect of an adult who has registered his or her objection to becoming a donor of his or her relevant organs in accordance with that section.
- (3) Where the Executive has made an entry in the Register, it shall contact the person in respect of whom the entry has been made, in the manner specified by the Executive, to confirm the details of the entry.
- (4) Only the Executive may access the information contained in the Register and the contents of the Register shall not be available to the public.
- (5) The Executive shall take such steps as it considers necessary to ensure that the particulars entered in the Register are accurate.
- (6) The Executive may, for the purposes of maintaining the accuracy of the Register and, where it considers it appropriate to do so, amend or delete any particulars entered in the Register.

#### **Application to register objection to being relevant organ donor**

- 33.** (1) An adult (in this section referred to as the “applicant”) may apply to the Executive to register his or her objection to being an organ donor of his or her relevant organs and where he or she does so, the Executive shall register that objection on the Register.
- (2) An application under *subsection (1)* shall—
- (a) be in writing, and
  - (b) subject to *subsection (3)*, be in such form and manner as is specified by the Executive.
- (3) When making an application under *subsection (1)*, an applicant shall provide the following information to the Executive:
- (a) his or her forename, surname and any former surnames;
  - (b) his or her mother’s birth surname;
  - (c) his or her sex;
  - (d) his or her nationality and date and place of birth;
  - (e) his or her personal public service number (if any) (within the meaning of section 262 of the Social Welfare Consolidation Act 2005);
  - (f) where known, his or her individual health identifier (within the meaning of the Health Identifiers Act 2014);
  - (g) such other information as the Executive may, from time to time, reasonably specify for the purposes of maintaining the Register.
- (4) A person may apply to the Executive to—



- (a) amend his or her information on the Register provided in accordance with *subsection (3)*, or
  - (b) withdraw his or her objection provided in accordance with *subsection (1)* and have his or her details removed from the Register.
- (5) An application under *subsection (4)* shall—
- (a) be in writing, and
  - (b) be in such form and manner as specified by the Executive.
- (6) An objection registered on the Register by a person under *subsection (1)* shall remain on the Register for the lifetime of that person unless he or she withdraws his or her objection in accordance with *subsection (4)(b)*.
- (7) A person shall not make—
- (a) an application under *subsection (1)* to register any person other than himself or herself on the Register, or
  - (b) an application under *subsection (4)(a)* or *(b)* in respect of the information or objection contained on the Register relating to any person other than himself or herself,
- without that person's knowledge and consent.
- (8) A person who contravenes *subsection (7)* shall be guilty of an offence.

#### **Application to ascertain if objection registered on Register**

34. (1) A relevant professional shall, for the purpose of determining whether or not deemed consent applies in respect of a deceased person, apply to the Executive to ascertain whether or not the deceased person has registered his or her objection to being an organ donor in accordance with *section 33*.
- (2) On receipt of an application under *subsection (1)*, the Executive shall, as soon as practicable, consult the Register and confirm whether or not the person the subject of the application has registered his or her objection to being an organ donor.
- (3) An application under *subsection (1)* shall be made in such form and manner as may be specified by the Executive.
- (4) Where a relevant professional has received information provided by the Executive in relation to a person in accordance with *subsection (2)*, he or she may disclose such information to the designated family member—
- (a) where the person the subject of the application has registered his or her objection to organ donation on the Register in accordance with *section 33* and the designated family member has enquired about potential organ donation relating to the person concerned, or

- (b) where the person the subject of the application has not registered his or her objection to organ donation on the Register in accordance with *section 33* and deemed consent applies to the proposed donation.
- (5) A relevant professional shall not remove any relevant organ for the purposes of transplantation activities from a person where the person has registered his or her objection to organ donation on the Register in accordance with *section 33* and that objection has not been withdrawn at the time of the person's death.

## CHAPTER 6

### *Compliance under Part and consequential amendments to Regulations of 2006 and Regulations of 2012*

#### **Authority to monitor compliance with Part 2**

- 35.** (1) Subject to *subsection (2)*, the Authority shall, in respect of transplantation activities relating to organs and tissues and cells, monitor compliance with this Part.
- (2) The functions conferred on the Authority under *subsection (1)* shall not include functions relating to authorisation, establishment, operation or maintaining of, or compliance with, the Panel or the Register.
  - (3) Summary proceedings for an offence under this Part (other than an offence under *section 33(8)*) may be brought and prosecuted by the Authority.

#### **Consequential amendments to Regulations of 2006**

- 36.** (1) The Regulations of 2006 are amended—
- (a) in Regulation 2—
    - (i) by the insertion of the following definitions:

*“ ‘Act of 2024’ means the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024;*

*‘relevant provisions of Part 2 of the Act of 2024’ means those provisions concerning transplantation activities relating to tissues and cells in respect of which the Authority is required to monitor compliance pursuant to section 35 of the Act of 2024;*”
  - and
  - (ii) in the definition of “inspection”, by the substitution of “these Regulations, the Regulations of 2007 and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Regulations of 2007”,
  - (b) in paragraphs (1) and (2) of Regulation 4, by the substitution of “the Directives, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directives and these Regulations” in both places where it occurs,
  - (c) in Regulation 6—

- (i) in paragraph (1)(a)(ii), by the substitution of “Regulations, the relevant provisions of *Part 2* of the *Act of 2024*” for “Regulations, or”,
  - (ii) in paragraph (1)(b)(iii), by the substitution of “the Directives, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directives and these Regulations”,
  - (iii) in paragraph (6)(a), by the insertion of “and the relevant provisions of *Part 2* of the *Act of 2024*” after “these Regulations”,
  - (iv) in paragraph (6)(b), by the insertion of “and the relevant provisions of *Part 2* of the *Act of 2024*” after “these Regulations”,
  - (v) in paragraph (11)(a), by the substitution of “the Directives, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directives and these Regulations”,
  - (vi) in paragraph (11)(b), by the substitution of “this Regulation and the relevant provisions of *Part 2* of the *Act of 2024*” for “this Regulation”,
  - (vii) in paragraph (11A)(iv), by the substitution of “the Directives, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directives and these Regulations”,
  - (viii) in paragraph (11A)(v), by the substitution of “this Regulation and the relevant provisions of *Part 2* of the *Act of 2024*”, for “this Regulation”, and
  - (ix) in paragraph (14), by the substitution of “the Directives, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directives and these Regulations”,
- (d) in Regulation 7—
- (i) by the substitution, in paragraph (1)(a), of “the Directives, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directives and these Regulations”, and
  - (ii) by the substitution, in paragraph (1)(b), of “the Directives, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directives and these Regulations”,
- (e) in Regulation 8, by the substitution, in paragraph (1)(a), of “these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations”,
- (f) in Regulation 9—
- (i) by the substitution, in paragraph (2), of “Schedule 4 and the relevant provisions of *Part 2* of the *Act of 2024*” for “Schedule 4”, and
  - (ii) by the substitution, in paragraph (4)(d)(ii), of “or compliance with the relevant provisions of *Part 2* of the *Act of 2024*, as appropriate” for “or authorisation”,
- (g) in Regulation 11—

- (i) by the substitution, in paragraph (3), of “Reproductive cells” for “Tissues and cells”,
  - (ii) by the deletion, in paragraph (3), of “(in the case of a living adult) or the next of kin (in the case of a deceased person or a person who is unable to give consent)”,
  - (iii) by the substitution, in paragraph (4), of “reproductive cells” for “tissues and/or cells in relation to living donors”,
  - (iv) by the deletion, in paragraph (4)(a), of “, or the donor, next of kin, (in the case of a person who is unable to give consent)”,
  - (v) by the substitution, in paragraph (4)(e), of “reproductive cells” for “tissue and/or cell”, and
  - (vi) by the deletion of paragraph (5),
- (h) in Regulation 13—
- (i) by the substitution, in paragraph (1), of “reproductive cells” for “human tissues and cells”,
  - (ii) by the substitution, in paragraph (2), of “reproductive cells” for “tissues and cells”,
  - (iii) by the substitution, in paragraph (3)(a), of “reproductive cells” for “human tissues and cells”, and
  - (iv) by the substitution, in paragraph (3)(b), of “reproductive cells” for “tissues and cells”,
- (i) in Regulation 19, by the substitution, of “these Regulations, the Regulations of 2007 and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Regulations of 2007” in each place where it occurs,
- (j) in Regulation 22—
- (i) in paragraph (1)—
    - (I) by the substitution of “Chief Executive of the Health Products Regulatory Authority,” for “IMB” in each place where it occurs, and
    - (II) by the substitution of “her or him” for “it”,and
  - (ii) by the substitution of “these Regulations or the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations” in each place where it occurs,
- (k) in Regulation 24, by the substitution of “these Regulations or the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations”,
- (l) in Regulation 26, by the substitution of “these Regulations, and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations”,

- (m) in Regulation 32(1), by the substitution of “these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations”,
- (n) in Schedule 4—
  - (i) by the substitution, in paragraph 1.1.1(a), of “Regulation 11 in relation to reproductive cells and in accordance with the relevant provisions of *Part 2* of the *Act of 2024* for all other tissues and cells” for “Regulation 11”,
  - (ii) by the substitution, in paragraph 1.1.2, of “In the case of living donors of reproductive cells” for “In the case of living donors”, and
  - (iii) by the substitution, in paragraph 2.4(a), of—
    - (I) “reproductive cells” for “tissues and cells”, and
    - (II) “reproductive cells” for “tissue or cells”,
 and
- (o) in Schedule 5, by the substitution of “Regulations 2006 and the relevant provisions of *Part 2* of the *Act of 2024*” for “Regulations 2006”.

### **Consequential amendments to Regulations of 2012**

#### **37. (1) The Regulations of 2012 are amended—**

- (a) in Regulation 2, by the insertion of the following definitions:
  - “ ‘*Act of 2024*’ means the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024*;
  - ‘relevant provisions of *Part 2* of the *Act of 2024*’ means the provisions concerning transplantation activities relating to organs with respect to which the Authority is required to monitor compliance pursuant to *section 35* of the *Act of 2024*;”,
- (b) in Regulation 4, by the substitution in paragraph (7), of—
  - (i) “the Directive, these Regulations and *section 35* of the *Act of 2024*” for “the Directive and these Regulations”, and
  - (ii) “*section 4(1)(x)*” for “*section 4(1)(v)*”,
- (c) in Regulation 5, by the substitution in paragraph (1), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directive”,
- (d) in Regulation 6—
  - (i) by the substitution in paragraph (1), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directive”, and

- (ii) by the substitution in paragraph (4)(a), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directive”,
- (e) in Regulation 8, by the substitution of the following paragraph for paragraph (3)(a):
  - “(a) the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*, or”,
- (f) in Regulation 9, by the substitution, in paragraph (1)(a), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directive”,
- (g) in Regulation 10—
  - (i) by the substitution, in paragraph (1)(a), of “the Directive, these Regulations, the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations, the Directive”, and
  - (ii) by the substitution, in paragraph (2)(a), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directives”,
- (h) in Regulation 11, by the substitution in paragraph (2)(a), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directive and these Regulations”,
- (i) in Regulation 12, by the substitution, in paragraph (1), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directive”,
- (j) in paragraph (3) of Regulation 15—
  - (i) by the substitution of “laid down in the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “laid down in these Regulations and the Directive”, and
  - (ii) by the deletion, in subparagraph (a), of “and provide him or her with the information he or she needs to understand the consequences of donation,”,
- (k) by the deletion of Regulations 21 and 22,
- (l) in Regulation 23, by the substitution, in paragraph (1), of the following subparagraph for subparagraph (b):
  - “(b) ensure that living donors are selected on the basis of their health and medical history, by suitably qualified or trained and competent professionals and in accordance with the relevant provisions of *Part 2* of the *Act of 2024*,”,
- (m) in Regulation 24, by the substitution—

- (i) in paragraph (1)(b), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directive”, and
- (ii) in paragraph (2), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directive”,
- (n) in Regulation 26, by the substitution in paragraph (1), of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations and the Directive”,
- (o) in Regulation 31, by the substitution of “the Directive, these Regulations and the relevant provisions of *Part 2* of the *Act of 2024*” for “the Directive and these Regulations” in each place where it occurs,
- (p) in Regulation 32—
  - (i) in paragraph (1)—
    - (I) by the substitution of “Chief Executive of the Health Products Regulatory Authority” for “IMB” in each place where it occurs, and
    - (II) by the substitution of “her or him” for “it”,and
  - (ii) by the substitution of “these Regulations or the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations” in each place where it occurs,
- (q) in Regulation 34, by the substitution of “these Regulations or the relevant provisions of *Part 2* of the *Act of 2024*” for “these Regulations” where it firstly occurs,
- (r) in Regulation 35—
  - (i) by the deletion, in paragraph (1), of “20, 21(1), (2) or (4)”, and
  - (ii) in paragraph (2)—
    - (I) by the substitution of “a person who” for “a person”,
    - (II) by the deletion, in subparagraph (a), of “who”,
    - (III) by the deletion of subparagraph (i),
    - (IV) by the substitution of the following subparagraph for subparagraph (j):
      - “(j) harbours, imports or exports an organ contrary to these Regulations and the Directive, or”,and
    - (V) by the deletion, in paragraph (k) of “who”,and

- (s) in the Schedule, by the substitution of “Regulations 2012 and the relevant provisions of *Part 2* of the *Act of 2024*” for “Regulations 2012” in each place where it occurs.

## PART 3

### PATHOLOGY PRACTICE

#### CHAPTER 1

#### *Preliminary and General*

#### **Definitions (*Part 3*)**

**38.** In this Part—

“Act of 2004” means the Health Act 2004;

“Authority” means the Health Information and Quality Authority;

“child” includes a stillborn child;

“coronial post-mortem examination” means a post-mortem examination directed by or on behalf of a coroner under the Coroners Acts 1962 to 2024 in relation to a deceased person;

“designated healthcare worker” means—

- (a) a registered medical practitioner,
- (b) a registered nurse or registered midwife within the meaning of section 2(1) of the Nurses and Midwives Act 2011,
- (c) a member of one or more of the following designated professions within the meaning of section 3 of the Health and Social Care Professionals Act 2005, namely:
  - (i) medical scientist;
  - (ii) psychologist;
  - (iii) social care worker;
  - (iv) social worker;
  - (v) such other designated profession within the meaning of the said section 3 of the said Act as the Minister considers appropriate and may prescribe by regulations under *section 3*,
- (d) an anatomical pathology technician, or
- (e) a staff member nominated for that purpose by the hospital concerned,

who by way of training and expertise has the relevant understanding and experience to



undertake functions under this Part;

“health service” means the provision, by or under the direction of a health services provider, of clinical care or any ancillary service to a patient for—

- (a) the screening (other than a cancer screening service), preservation or improvement of the health of the patient,
- (b) the prevention, diagnosis, treatment or care of an illness, injury or health condition of the patient,
- (c) the performance of surgery, or a surgical intervention, in respect of aesthetic purposes, or other non-medical purposes, that involves instruments or equipment being inserted into the body of the patient, or
- (d) without prejudice to *paragraph (a)*, a cancer screening service;

“hospital” shall be construed in accordance with *section 39*;

“mother”, in relation to a foetus, means the woman who carried the foetus;

“nominated person” has the meaning assigned to it by *section 52*;

“non-coronial post-mortem examination” means the examination of the body of a deceased person (including a foetus or stillborn child) involving its dissection and the removal of part of a body which is carried out for a purpose specified in *section 44* and includes—

- (a) removal of tissue for diagnostic purposes and the retention of small samples of same as histological blocks and slides to form part of the post-mortem record, and
- (b) for the purposes of a non-coronial post-mortem examination of a foetus, a laboratory examination performed on the foetus for any of the purposes specified in that section;

“part of a body” means any part of the human anatomy and includes but is not limited to—

- (a) an organ,
- (b) tissue,
- (c) a limb or part of a limb,
- (d) blood or any material derived from blood, or
- (e) any other biological fluid;

“post-mortem examination report” has the meaning assigned to it by *section 46*;

“private hospital” means a hospital under the management or control of a person (other than the Executive)—

- (a) at which—
  - (i) medical or surgical treatment for illness, injury, disability, palliative, obstetric or gynaecological care, or

(ii) a health service, is provided to a person which provision of treatment is under the direction of registered medical practitioners from at least 3 different medical specialities who are registered in the Specialist Division of the register of medical practitioners,

and

(b) which is capable of accommodating one or more persons in that hospital when providing the treatment under *paragraph (a)*, for a minimum period of 24 hours, but does not include—

(i) a designated centre (within the meaning of the Health Act 2007),

(ii) a centre registered by the Mental Health Commission,

(iii) a provider of a health service who enters into an arrangement under section 38 of the Act of 2004 to provide a health or personal social service on behalf of the Executive, or

(iv) a hospital which is in receipt of assistance under section 39 of the Act of 2004;

“stillborn child” has the same meaning as it has in section 2(1) of the Civil Registration Act 2004.

### **Application of Part**

**39.** (1) Subject to *subsection (2)*, this Part shall apply to post-mortem activities and coronial post-mortem examinations that take place on or after the commencement of this section in a hospital (whether public or private) and a reference in this Part to a “hospital” includes a reference—

(a) to a private hospital, and

(b) to a facility (howsoever described) other than a hospital or relevant facility, within the meaning of section 2 of the Act of 1962, where post-mortem activities are carried out in accordance with this Part by service providers (within the meaning of section 2 of the Health Act 2004), pursuant to section 38 of that Act.

(2) This Part shall not apply to—

(a) post-mortem activities which were commenced but not completed before the coming into operation of *subsection (1)*, and

(b) subject to the operation as necessary of sections 33(2B), 33(2C), 33(2D), 33(3A), 33(3B), 33(3C), 33(3D), 33F, 33G, 33H, 33I, 33J, 33K, 33L, 33M, 33N and 33O of the Act of 1962, coronial post-mortem examinations.

### **Regulations for purposes of Part, including regulations to apply to certain aspects of coronial post-mortem examinations that take place in hospitals**

**40.** (1) Subject to *subsections (3) and (4)*, the Minister may make such regulations as he or she considers necessary or expedient for the management in the most respectful and

appropriate manner possible of post-mortem activities and coronial post-mortem examinations that take place in a hospital.

- (2) Without prejudice to the generality of *subsection (1)*, regulations under *subsection (1)* may provide for all or any of the following matters:
  - (a) procedures for the retention, storage, disposal or return of material removed from the body as part of the coronial or non-coronial post-mortem examination, where such action is consistent with guidelines but shall not include tissue samples held on blocks or slides, trimmings or bodily fluids removed during the examination;
  - (b) the arrangements to be put in place by hospitals for—
    - (i) the management of authorisations (within the meaning of section 2 of the Act of 1962) under section 33F of that Act,
    - (ii) the designation of persons or classes or persons responsible for the management of such authorisations, and
    - (iii) the carrying out of the authorisations received from the coroner in that regard;
  - (c) incidents and particulars of incidents to be notified to the Authority;
  - (d) prescribing the retention periods for records and samples arising from non-coronial post-mortem activities, each of which periods (other than in the case of records and samples which are toxicology samples, trimmings or bodily fluids) shall not be less than 5 years;
  - (e) any other matters which are necessary or expedient for the purposes of giving effect to *subsection (1)*.
- (3) Before making regulations under *subsection (1)*, the Minister shall consult such persons as he or she considers appropriate including all or any of the following:
  - (a) the Executive;
  - (b) the Authority;
  - (c) the Minister for Justice;
  - (d) the Chief State Pathologist;
  - (e) a representative of the Coroners Society of Ireland;
  - (f) a pathologist from the Royal College of Physicians of Ireland, Faculty of Pathology;
  - (g) a relevant patient advocacy group.
- (4) For the avoidance of doubt, nothing in *section 39*, this section or regulations made thereunder shall operate to prevent a coroner or any other person from complying with his or her obligations under the Coroners Acts 1962 to 2024.

## CHAPTER 2

*Consent and post-mortem activities***Consent - general provisions****41.** (1) For the purposes of this Part—

- (a) (i) post-mortem consent shall be in writing and shall be signed by the person giving the consent in the presence of one witness who shall attest the person's signature, or
- (ii) in a case where the person cannot provide consent in writing, post-mortem consent may be given orally by the person in the presence of two witnesses each of whom shall attest that the person gave consent,
- (b) (i) subject to *subparagraph (ii)* post-mortem consent in relation to a post-mortem activity may, at any time, be withdrawn or amended in the manner specified in *subparagraph (i)* or *(ii)* of *paragraph (a)*, and
- (ii) post-mortem consent in relation to a non-coronial post-mortem examination or the recording of such examination may, at any time prior to the commencement of that post-mortem examination, be withdrawn or amended in the manner specified in *subparagraph (i)* or *(ii)* of *paragraph (a)*,
- (c) post-mortem consent given by a person is given, and given only, for the purposes of the post-mortem activities, specified in the consent concerned,
- (d) where post-mortem consent is given by a person for the purposes of the post-mortem activities specified in the consent, it shall not be necessary to seek consent in respect of subsequent use provided that the use is only for the purposes specified in the consent concerned,
- (e) a copy of a post-mortem consent, together with a copy of any withdrawal or amendment of the consent shall be—
  - (i) retained with the medical records of the deceased person or, in the case of a foetus, in accordance with the procedures of the hospital concerned and any guidelines made in that regard,
  - (ii) retained with the records of the hospital where the non-coronial post-mortem examination occurred for such period as shall be prescribed in regulations under *section 40*, and
  - (iii) made available to the person who gave the consent,and
- (f) post-mortem consent may be limited to—
  - (i) the non-coronial post-mortem examination and the burial, cremation or return, in accordance with regulations under *section 40(2)(a)*, of any part of a

body removed as part of that non-coronial post-mortem examination, other than any tissue removed and retained in accordance with *section 43(3)*,

- (ii) the non-coronial post-mortem examination and any other post-mortem activities specified in the consent,
  - (iii) a specific region of the body, or
  - (iv) particular tissues and organs.
- (2) When seeking post-mortem consent for post-mortem activities to be carried out in accordance with *section 47, 48, 49 or 50* a designated healthcare worker shall, in accordance with any guidelines, provide the following information to a relevant person:
- (a) information sufficient to enable the relevant person to understand what the proposed post-mortem activities shall entail before post-mortem consent is provided;
  - (b) an indication of the parts of the body which are likely to be removed from the deceased adult, child or foetus;
  - (c) the types of information available to enable the relevant person to make an informed decision regarding the proposed post-mortem activities;
  - (d) confirmation of the relevant person's entitlement to receive information on the proposed post-mortem activities either before or after he or she provides consent in relation to such activities;
  - (e) any information that it would be reasonable, on the request of the relevant person, for the designated healthcare worker to provide to the relevant person in relation to post-mortem activities before or after such activities take place;
  - (f) information on the options available to the relevant person in relation to the subsequent burial, cremation or return, in accordance with regulations under *section 40(2)(a)*, of any part of a body retained following the post-mortem activities;
  - (g) an indication of the length of time a part of a body may, in accordance with regulations under *section 40(2)(a)*, be retained and what the subsequent use, if any, of such part of a body may be;
  - (h) in the case of the proposed retention and use of any part of a body, including for the use by a third party, information relating to the types of use that this may entail;
  - (i) in the case of the proposed retention and use of any organ or tissue, including for the use for commercial purposes, information relating to types of commercial use that this may entail and the effect of *section 50*;
  - (j) confirmation that the post-mortem examination report shall be available to the relevant person at his or her request.
- (3) In this section, "relevant person" means—

- (a) in relation to a deceased adult in respect of whom it is proposed to carry out a non-coronial post-mortem examination—
  - (i) the adult, the subject of the examination where he or she has, prior to his or her death, consented to a non-coronial post-mortem examination being carried out on his or her body, or
  - (ii) the designated family member of the deceased adult where the deceased adult has not, prior to his or her death, consented to a non-coronial post-mortem examination being carried out on his or her body,
- (b) in relation to a deceased child in respect of whom it is proposed to carry out a non-coronial post-mortem examination, a parent or guardian of the deceased child, or
- (c) in relation to a foetus in respect of whom it is proposed to carry out a non-coronial post-mortem examination, the mother or a person acting on her behalf.

**Post-mortem activities**

- 42.** (1) A person shall not carry out a post-mortem activity unless he or she is satisfied that post-mortem consent has been provided.
- (2) For the purposes of this Part, “post-mortem activities” means all or any of the following:
- (a) a non-coronial post-mortem examination;
  - (b) the retention, by the hospital where the non-coronial post-mortem examination took place, of any part of a body removed from the body of a deceased person or foetus during the examination, other than a retention referred to in the definition of “non-coronial post-mortem examination”;
  - (c) the use of any part of a body retained after a non-coronial post-mortem examination, including the use of any part of a body by a third party;
  - (d) the use of any organ or tissue retained after a non-coronial post-mortem examination, including the use of any part of a body for commercial purposes;
  - (e) the audio, visual or photographic recording of a non-coronial post-mortem examination;
  - (f) the burial, cremation or return, in accordance with regulations under *section 40(2)(a)*, of any part of the body removed as part of a non-coronial post-mortem examination, other than any tissue, trimmings or biological fluids removed as part of the examination.
- (3) A person who contravenes *subsection (1)* shall be guilty of an offence.

**Removal and retention of organs and other body parts during non-coronial post-mortem examination**

43. (1) Where post-mortem consent is provided for a non-coronial post-mortem examination, any part of a body of a deceased adult, child or foetus on whose body the examination is performed may, by virtue of such consent, be removed from the body during the non-coronial post-mortem examination and used thereafter for the purposes of such examination.
- (2) Where part of a body is removed in accordance with *subsection (1)*, a tissue sample may be taken from that part and retained in accordance with *subsection (3)*.
- (3) A tissue sample removed for diagnostic purposes during a non-coronial post-mortem examination in accordance with *subsection (2)* and held on blocks or slides for this purpose shall be retained in the records of the hospital that carried out the examination for such period as shall be prescribed under *section 40* and shall—
- (a) in the case of a non-coronial post-mortem examination of an adult or child, form part of the medical records of the adult or child concerned, or
- (b) in the case of a non-coronial post-mortem examination of a foetus, form part of the medical records specified for that purpose in accordance with the procedures of the hospital concerned and any guidelines made in that regard.
- (4) A part of a body, other than a part of a body indicated in that behalf under *section 41(2)(b)* as likely to be removed, shall not be removed from a body during a non-coronial post-mortem examination.
- (5) The removal of any part of a body during a non-coronial post-mortem examination, other than for the purpose of that examination, shall require post-mortem consent.
- (6) A person or hospital shall not receive financial compensation or other non-financial inducements for any part of a body removed during a non-coronial post-mortem examination.
- (7) Subject to *section 50*, any part of a body removed during a non-coronial post-mortem examination shall not be used for commercial purposes.
- (8) A part of a body that was removed during the course of a non-coronial post-mortem examination carried out before the date on which this section comes into operation, may be retained to be used for purposes associated with the non-coronial post-mortem examination without post-mortem consent but such part of a body shall not be sold or used for commercial purposes other than in accordance with the post-mortem consent.

**Purposes for which post-mortem activities may be undertaken**

44. A post-mortem activity may only be undertaken where the activity is carried out for one or more of the following purposes:
- (a) determining or providing further information on the medical cause of death of the adult, child or foetus concerned;

- (b) providing information to the designated family member or medical professional on the effectiveness of any medical or surgical intervention by a registered medical practitioner or the progression of a medical condition;
- (c) obtaining scientific or medical information which may be of benefit to other persons and which information is important for assessing and improving the quality of medical care;
- (d) medical research including research into the nature, causes and prevention of disease;
- (e) undertaking non-coronial post-mortem examinations for purposes of education and training of healthcare professionals and medical and nursing students;
- (f) undertaking non-coronial post-mortem examinations for purposes of clinical audit and quality assurance.

#### **Carrying out of non-coronial post-mortem examination**

- 45.** (1) Without prejudice to the generality of *section 42*, a non-coronial post-mortem examination shall not be carried out by a person unless the person—
- (a) is a pathologist or a registered medical practitioner under the supervision of a pathologist, and
  - (b) is satisfied the post-mortem consent, where appropriate, has been provided in accordance with *section 47, 48, 49 or 50*.
- (2) A pathologist or a registered medical practitioner under the supervision of a pathologist may, when carrying out a non-coronial post-mortem examination in accordance with *subsection (1)*, be assisted (whether by way of technical or clinical assistance) in carrying out such examination by an appropriately qualified healthcare professional or other person who, in the opinion of the pathologist carrying out or supervising the non-coronial examination, is sufficiently qualified or has the relevant training to provide such assistance.
- (3) Where a non-coronial post-mortem examination has been carried out in accordance with *subsection (1)* the pathologist who carried out the examination shall maintain, or cause to be maintained, a written record of any part of a body retained in accordance with *section 46(3)*.
- (4) A person who contravenes—
- (a) *subsection (1)*, or
  - (b) *subsection (3)*,
- shall be guilty of an offence.
- (5) In this section, “technical or clinical assistance” in relation to the carrying out of a non-coronial post-mortem examination, includes, the removal by a person providing the assistance, of a part of a body from the deceased adult, child or foetus, the subject of the examination concerned.



**Report of post-mortem examination**

46. (1) A pathologist who has carried out or supervised a non-coronial post-mortem examination in accordance with *section 45* shall make a report, in writing, of the examination (in this Part referred to as a “post-mortem examination report”).
- (2) A post-mortem examination report shall contain information obtained as a result of the non-coronial post-mortem examination including the findings of the examination and such other matters as may be provided for in guidelines.
- (3) A copy of a report under *subsection (1)* shall—
- (a) be retained—
- (i) with the medical records of the deceased adult or child, the subject of that non-coronial post-mortem examination, or
- (ii) in the case of a non-coronial post-mortem examination of a foetus, in accordance with the procedures of the hospital concerned and any guidelines made in that regard,
- and
- (b) be retained for such period as shall be prescribed under *section 40*, by the hospital in which the non-coronial post-mortem examination takes place and shall, during that period, be made available, on request, to a person who gave consent under *section 47, 48 or 49*.

**Consent for post-mortem activities on adult**

47. (1) An adult may, prior to his or her death, consent to post-mortem activities to be performed on his or her body after his or her death.
- (2) When it is proposed to carry out post-mortem activities on a deceased adult who has not consented to post-mortem activities in accordance with *subsection (1)*, a designated healthcare worker shall seek post-mortem consent for the post-mortem activities from the designated family member of the deceased adult and the designated family member may consent to the post-mortem activities concerned.
- (3) Where a designated family member is considering whether to provide post-mortem consent under *subsection (2)*, the designated family member shall consider whether or not he or she believes that the deceased person would have objected to the post-mortem activities concerned.

**Consent for post-mortem activities on deceased child**

48. (1) When it is proposed to carry out post-mortem activities on a deceased child, a designated healthcare worker shall seek post-mortem consent for the post-mortem activities from a parent or guardian of the child and the parent or guardian may consent to the post-mortem activities concerned.

- (2) A parent or guardian of a deceased child may consent to post-mortem activities on the deceased child notwithstanding that the parent has not yet attained the age of 18 years.
- (3) A parent or guardian, when providing post-mortem consent under *subsection (1)*, shall have regard to any previously expressed wishes of the deceased child, in proportion to the child's age, degree of maturity and decision-making capacity at the time of expressing those wishes.
- (4) Where one of the parents or guardians of a deceased child has provided post-mortem consent in accordance with *subsection (1)* ("the first parent or guardian") and the other parent or guardian objects to the consent provided by the first parent or guardian, the post-mortem activities shall not proceed.

#### **Consent for post-mortem activities on foetus**

49. (1) When it is proposed to carry out post-mortem activities on a foetus, a designated healthcare worker shall seek post-mortem consent for the post-mortem activities from the mother of the foetus or a person acting on her behalf and the mother, or person acting on her behalf, may consent to the post-mortem activities concerned.
- (2) Where the mother of the foetus has not yet attained the age of 18 years she may, notwithstanding that fact, consent to post-mortem activities on the foetus.

#### **Commercial purposes and consent for use**

50. (1) Where it is intended that a part of a body of—
  - (a) a deceased child,
  - (b) a deceased adult, or
  - (c) a deceased foetus,

which is removed during a non-coronial post-mortem examination be retained and used for commercial purposes, including use by a pharmaceutical company, the person in charge of the hospital concerned shall in accordance with guidelines first give his or her approval.

- (2) Subject to *subsection (10)*, a person in charge of a hospital may where he or she is satisfied it is appropriate to do so, and, in accordance with guidelines, approve the retention of a part of a body of a deceased child, deceased adult or deceased foetus for commercial use.
- (3) Subject to *section 41* and the provisions of this section, an approval given under *subsection (2)*, is approval for the commercial use of that part of the body.
- (4) Where the person in charge of a hospital has, in accordance with guidelines, approved the retention of a part of a body for commercial use under *subsection (2)* in respect of a deceased child, a registered medical practitioner shall seek post-mortem consent from a parent or guardian of the deceased child for the use of such part of a body for commercial purposes and, notwithstanding such approval, unless such consent is obtained, the part of a body shall not be used for those purposes.

- (5) Where the person in charge of a hospital has, in accordance with guidelines, approved the retention of a part of a body for commercial use under *subsection (2)* in respect of a deceased adult, a registered medical practitioner shall seek post-mortem consent from a designated family member for the use of such part of a body for commercial purposes and, notwithstanding such approval, unless such consent is obtained, the part of a body shall not be used for those purposes.
- (6) Where the person in charge of a hospital has approved the retention of a part of a body for commercial use under *subsection (2)*, in respect of a deceased foetus, a registered medical practitioner shall seek post-mortem consent from the mother of the foetus or a person acting on her behalf for the use of such part of a body for commercial purposes and, notwithstanding such approval, unless such consent is obtained, the part of a body shall not be used for those purposes.
- (7) Where post-mortem consent has been provided in accordance with *subsection (4), (5) or (6)* and the part of a body retained from a non-coronial post-mortem examination is supplied to a third party, any arrangement in relation to such supply shall, in accordance with guidelines, be recorded and approved in writing by the person in charge of the hospital in which the non-coronial post-mortem examination took place.
- (8) Records referred to in *subsection (7)* shall be retained by the hospital for such period as shall be prescribed under *section 40*.
- (9) Without prejudice to the generality of *section 6*, the Minister shall issue guidelines in relation to the procedures for approval for the retention of parts of a body for commercial purposes.
- (10) A person or hospital shall not receive financial compensation or other non-financial inducements for any part of a body removed during a non-coronial post-mortem examination.
- (11) In this section, “person in charge” means, in relation to a hospital—
  - (a) the chief executive officer (howsoever described) of the hospital,
  - (b) the owner of the hospital, or
  - (c) a suitably qualified person specified in that behalf for the purposes of this Act by a person referred to in *paragraph (a)*.

#### **Application by Minister to High Court**

- 51.** (1) The Minister may make an application to the High Court (in this section referred to as the “Court”) to seek an order permitting a non-coronial post-mortem examination on a deceased adult, child or foetus, without post-mortem consent under *section 47, 48 or 49*, as the case may be, in exceptional circumstances including—
- (a) where such non-coronial post-mortem examination is required in the interests of public health, and
  - (b) where there is a risk to public health if a non-coronial post-mortem examination is not carried out.

- (2) The Court may make an order permitting a non-coronial post-mortem examination on a deceased adult, child or foetus, dispensing with the requirement of post-mortem consent where the court is satisfied that there are such exceptional circumstances as to warrant the making of the order.
- (3) The Court shall not make an order under *subsection (2)* where it is satisfied that to do so would be contrary to the public interest.
- (4) When the Court is determining whether or not to dispense with the requirement of post-mortem consent in accordance with *subsection (2)*, the Court shall have due regard—
  - (a) in the case of a deceased adult—
    - (i) to the rights and concerns of the designated family member, and
    - (ii) to the rights and views of the deceased adult (if known),
  - (b) in the case of a deceased child, to the rights and concerns of the parents or guardians of the deceased child and, if known, the rights and views of the deceased child,
  - (c) in the case of a deceased foetus, to the rights and concerns of the mother of the deceased foetus or, in a case where the mother is deceased, to the rights and concerns of the designated family member of the deceased mother and, if known, the rights and views of the deceased mother,
  - (d) to the significance and urgency of the matter the subject of the decision,
  - (e) to the risk to public health in not conducting a non-coronial post-mortem examination on the deceased adult, child or foetus, the subject of the application, and
  - (f) to any other matter the court considers appropriate having regard to the circumstances of the application.
- (5) Subject to *subsection (6)*, notice of every application under this section shall be given to—
  - (a) where the subject of the application is a deceased adult, the designated family member of the deceased adult,
  - (b) where the subject of the application is a deceased child, the parent or guardian of the deceased child, or
  - (c) where the subject of the application is a deceased foetus, the mother of the deceased foetus, or, where the mother is deceased, the designated family member of the deceased mother.
- (6) The Court may give directions relating to the manner of giving notice to a person under this section and may deem any notice given to be sufficient or may, on sufficient cause being shown, dispense with the giving of notice of the application.

**Nominated person**

- 52.** (1) A hospital at which post-mortem activities or coronial post-mortem examinations, as the case may be, take place or will take place shall, subject to *subsection (2)*, as soon as practicable after the commencement of this section and, in any event, not later than 12 weeks after such commencement, nominate in writing at least one suitably qualified person for the purposes of this Part (in this Part referred to as a “nominated person”).
- (2) A nominated person shall be an employee of the hospital concerned and shall be a suitably qualified person by reason of his or her training and experience to discharge the responsibilities of a nominated person.
- (3) A nominated person shall have the following responsibilities namely:
- (a) to ensure that an internal audit of post-mortem activities or coronial post-mortem examinations that take place in the hospital is maintained;
  - (b) to ensure that an annual report of post-mortem activities or coronial post-mortem examinations that take place in the hospital is compiled and submitted to the Authority;
  - (c) to maintain or cause to be maintained records in accordance with this Part;
  - (d) without prejudice to the powers of the Authority under this Part to monitor compliance with this Part, to notify the Authority in writing when he or she becomes aware of any breach of a provision of this Part;
  - (e) to liaise with the Authority from time to time and when requested to do so by the Authority.
- (4) A hospital in which post-mortem activities or coronial post-mortem examinations take place or will take place shall inform the Authority of the name and particulars of the person nominated under *subsection (1)*.
- (5) A nominated person shall, in accordance with any guidelines, notify the Authority as soon as practicable, but no later than 3 months after the commencement of this section, of the post-mortem activities which take place in the hospital in relation to which he or she is the nominated person.
- (6) A hospital at which post-mortem activities or coronial post-mortem examinations take place shall, notwithstanding the nomination by the hospital of a nominated person, at all times remain responsible for, and accountable to the Authority in respect of, compliance with this Part.

**Authority to monitor compliance with Part 3 – authorised persons, etc.**

- 53.** (1) The Authority shall monitor compliance with this Part.
- (2) An authorised person appointed under section 70 of the Health Act 2007 shall be deemed to be an authorised person for the purposes of this Part.
- (3) The Health Act 2007 is amended—

(a) in section 2, by the insertion of the following definitions:

“ ‘Act of 1962’ means the Coroners Act 1962;

‘coronial post-mortem examination’ has the same meaning as it has in section 38 of the *Act of 2024*;

‘non-coronial post-mortem examination’ has the same meaning as it has in section 38 of the *Act of 2024*;

‘relevant facility’ has the same meaning as it has in section 2 of the Act of 1962;

‘relevant sections of the Act of 1962’ means sections 33(2B), 33(2C), 33(2D), 33(3A), 33(3B), 33(3C), 33(3D), 33F, 33G, 33H, 33I, 33J, 33K, 33L, 33M, 33N and 33O”;

(b) in section 8(1)—

(i) in paragraph (n), to substitute “(S.I. No. 256 of 2018);” for “(S.I. No. 256 of 2018).”, and

(ii) by the insertion of the following paragraphs after paragraph (n):

“(o) to monitor compliance with *Part 3* of the *Act of 2024* and any regulations made under that Part;

(p) to monitor compliance with the relevant sections of the Act of 1962 and with any regulations made by the Minister for Justice under section 33I of that Act.”.

(c) by the insertion of the following section after section 12:

**“Provision of information to Authority for purposes of monitoring compliance with *Part 3* of *Act of 2024* and relevant sections of Act of 1962 in accordance with subsection (1)(o) and (1)(p) of section 8**

**12A.** (1) A hospital, within the meaning of section 39 of the *Act of 2024*, at which post-mortem activities or coronial post-mortem examinations take or will take place shall, as soon as practicable after the commencement of this section and in any event, not later than 3 months after such commencement, notify the Authority in writing of the following, namely:

(a) the name and particulars of the nominated person nominated in that behalf pursuant to section 52 of the *Act of 2024*;

(b) in the case of a hospital where post-mortem activities or coronial post-mortem examinations take place or will take place, the name and address of the hospital;

(c) in the case of a hospital where post-mortem activities or coronial post-mortem examinations take place or will take place, the details

of post-mortem activities or coronial post-mortem examinations that take place or will take place on the premises.

- (2) Where the hospital changes in a material way any of the matters notified under subsection (1), the hospital shall as soon as possible and, in any event, not later than 28 days after the material changes, inform the Authority in writing and provide it with details of the changes.
  - (3) Without prejudice to the generality of subsection (1), the Authority may require the Executive or the hospital at which the post-mortem activities or coronial post-mortem examinations take place or will take place to provide it within such reasonable period as the Authority may require with any information or statistics the Authority requires in order to determine the level of compliance by the Executive or hospital with *Part 3* of the *Act of 2024*.
  - (4) Where a person receives a request under subsection (3) from the Authority, he or she shall comply with such request.”
- (d) in section 70—
- (i) in subsection (1)(a), by the substitution of “section 8(1)(c),” for “section 8(1)(c), or”,
  - (ii) by the insertion, in subsection (1), of the following paragraphs after paragraph (b):
    - “(c) monitoring compliance with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o), or
    - (d) monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,”
  - (iii) in subsection (2)(a), by the substitution of “section 8(1)(c),” for “section 8(1)(c), or”, and
  - (iv) by the insertion, in subsection (2), of the following paragraphs after paragraph (b):
    - “(c) monitoring compliance with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o), or
    - (d) monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act.”
- (e) in section 73—
- (i) by the substitution of the following subsection for subsection (1):
    - “(1) If an authorised person considers it necessary or expedient for the purposes of—

- (a) monitoring compliance with standards in accordance with section 8(1)(c),
- (b) an investigation referred to in section 8(1)(d),
- (c) monitoring compliance with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o), or
- (d) monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,

the authorised person may enter and inspect at any time—

- (i) any premises owned or controlled by the Executive, the Agency or a service provider,
- (ii) any premises used or proposed to be used, for any purpose connected with the provision of services described in section 8(1)(b), or
- (iii) any relevant facility.”,

(ii) by the insertion of the following after subsection (3):

“(3A) If an authorised person considers it necessary or expedient for the purposes of monitoring compliance—

- (a) with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o), or
- (b) with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act in accordance with section 8(1)(p),

the authorised person, at any time, may carry out the functions conferred on the authorised person under this section and sections 75 and 76 to the extent that the functions relate to any premises referred to in subsection (1).”

(iii) in subsection (4)—

(I) by the substitution of the following paragraph for paragraph (a):

“(a) inspect, take copies of or extracts from and remove from the premises any documents or records (including personal records) relating to the discharge of its functions by the Executive or the Agency or the discharge of the functions of the coroner in so far only as it relates to monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act, or to the services provided by a service provider or at a designated centre.”,



and

(II) in paragraph (c)(i), by the substitution of “section 8(1)(d), or monitoring compliance with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o), or monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act” for “section 8(1)(d)”,

(iv) in subsection (5)(b)—

(I) in subparagraph (i), by the substitution of “section 8(1)(d), or monitoring compliance with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o) or monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,” for “section 8(1)(d)”, and

(II) in subparagraph (ii), by the substitution of “investigation or to the monitoring of compliance with regulations or,” for “investigation or,”,

and

(v) in subsection (7)—

(I) in paragraph (a), by the substitution of “section 8(1)(c),” for “section 8(1)(c), or”, and

(II) by the insertion of the following paragraphs after paragraph (b):

“(c) monitoring compliance with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o), or

(d) monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,”,

(f) in section 75—

(i) in subsection (1)(a), by the substitution of “section 8(1)(d) or monitoring compliance with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o) or monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act” for “section 8(1)(d)”, and

(ii) in subsection (2)(a)(i), by the substitution of “section 8(1)(d) or monitoring compliance with *Part 3* of the *Act of 2024* in accordance with section 8(1)(o) or monitoring compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act” for “section 8(1)(d)”,

and

(g) in section 77A(2), to substitute the following paragraph for paragraph (a):

“(a) the monitoring of compliance with standards under section 8(1)(c), compliance with *Part 3* of the *Act of 2024* under section 8(1)(o) and compliance, under section 8(1)(p), with the relevant sections of the Act of 1962 and any regulations made by the Minister for Justice under section 33I of that Act,”.

### **Compliance notices**

- 54.** (1) Where an authorised person is of the opinion that there is non-compliance by a person with a requirement of provisions of this Part or any regulations made under it, the authorised person may, following consultation with the Chief Executive Officer of the Authority or such other officer of the Authority so designated for that purpose, serve, or cause to be served, on the person concerned a notice (in this Part referred to as a “compliance notice”) in accordance with this section.
- (2) A compliance notice shall be signed by the authorised person who is issuing the notice or the person referred to in *subsection (1)* whom he or she consulted with in relation to the notice concerned and shall—
- (a) specify the requirement of this Part or the regulations made thereunder with which there has not been compliance,
  - (b) for the purposes of ensuring compliance by the person concerned, require the person by such date as is specified in the notice to do or refrain from doing such act or acts as is or are so specified in the notice,
  - (c) contain information regarding the bringing of an appeal under *section 55* against the notice, including information on the manner in which any such appeal shall be brought.
- (3) A compliance notice shall, unless an appeal is brought under *section 55*, come into operation on the expiry of 14 days from the date of service of the notice.
- (4) Where a person on whom a compliance notice has been served fails to comply with the notice at any time on and after the date on which the notice comes into operation, he or she shall be guilty of an offence and shall be liable on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both.
- (5) Summary proceedings for an offence under *subsection (4)* may be brought and prosecuted by the Authority.

### **Appeal of compliance notice**

- 55.** (1) A person on whom a compliance notice has been served may within 14 days of service of the compliance notice appeal to the District Court in respect of the notice or any requirement therein.
- (2) Where an appeal is brought under this section, the District Court may—
- (a) confirm the compliance notice, or
  - (b) direct the authorised person to withdraw the compliance notice concerned.

- (3) Where the District Court makes an order under *subsection (2)(b)*, the compliance notice shall cease to have effect.
- (4) Where the District Court confirms a compliance notice, the notice as so confirmed, shall come into operation on the expiry of 14 days of the date of confirmation or such later date as the court may determine.
- (5) The jurisdiction conferred on the District Court under this section shall be exercised by a judge of that court for the time being assigned to the district court district in which the person on whom the compliance notice is served ordinarily resides or carries on any profession, business or occupation.

### **Prohibition orders**

**56.** (1) Where an authorised person is of the opinion that—

- (a) there is a serious and material non-compliance with a requirement of the provisions of this Part or the regulations made thereunder, and
- (b) there is—
  - (i) a need in the public interest to immediately cease any or all of the post-mortem activities or coronial post-mortem examinations, the subject of opinion concerned, or
  - (ii) a failure to comply with a compliance notice,

the authorised person may, with the approval of the Chief Executive Officer of the Authority, or another officer of the Authority designated for that purpose, serve, or arrange to have served, on the person concerned, an order (in this Part referred to as a “prohibition order”) in accordance with *subsection (2)*.

- (2) A prohibition order shall be signed by the authorised person issuing it, or the person referred to in *subsection (1)* who approves the issuing of the prohibition order and shall—
  - (a) state that the authorised person is of the opinion that one or more of the grounds specified in *subsection (1)* for the serving of a prohibition order exists,
  - (b) specify the particular serious and material non-compliance, public interest need or failure, as the case may be, at issue,
  - (c) where relevant, identify the part or parts of the compliance notice with which there has not been compliance, and
  - (d) as appropriate, direct the person served with the order to cease, or arrange for the cessation of any or all of the post-mortem activities or coronial post-mortem examinations specified in the order concerned.
- (3) The approval referred to in *subsection (1)* may be given orally or in writing and if given orally shall be recorded in writing as soon as practicable.
- (4) A prohibition order shall take effect—

- (a) where the prohibition order so declares, immediately upon receipt of the order by the person on whom it is served, or
  - (b) in any other case—
    - (i) where no appeal is taken against the prohibition order, on the expiration of the period during which such an appeal may be taken or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later, or
    - (ii) where an appeal is taken, on the day next immediately following the day on which the prohibition order is confirmed on appeal or withdrawn or the day specified in the prohibition order as the date on which it is to come into effect, whichever is the later.
- (5) The bringing of an appeal against a prohibition order which is to take effect in accordance with *subsection (4)(a)* shall not have the effect of suspending the operation of the prohibition order, but the appellant may apply to the District Court to have the operation of the prohibition order suspended until the appeal is disposed of and, on such application, the District Court may, if it thinks it proper to do so, direct that the operation of the prohibition order be suspended until the appeal is concluded.
- (6) In the event of non-compliance or delay by the person on whom the prohibition order has been served, an authorised person shall, with the approval of the Chief Executive Officer or another officer designated for that purpose by the Authority, take whatever steps are considered necessary to ensure compliance with the direction given under this section.
- (7) A person on whom a prohibition order is served who is aggrieved by a prohibition order may, within the period of 7 days beginning on the day on which the prohibition order is served on him or her, appeal against the order to a judge of the District Court in the District Court district in which the prohibition order was served on him or her and, in determining the appeal the judge may—
- (a) if he or she is satisfied that in the circumstances of the case it is reasonable to do so, confirm the prohibition order, with or without modification, or
  - (b) where he or she is not so satisfied of the matters referred to in *paragraph (a)*, allow the appeal and cancel the prohibition order.
- (8) Where on the hearing of an appeal under this subsection a prohibition order is confirmed, notwithstanding *subsection (5)*, the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition order for such period as in the circumstances of the case the judge considers appropriate.
- (9) A person who appeals against a prohibition order or who applies for a direction suspending the application of the prohibition order under *subsection (5)* shall at the same time notify the Authority of the appeal or the application and the grounds for the appeal or the application and the Authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or the application.

- (10) The Board of the Authority shall be notified at the next available meeting of the Board of the service of a prohibition order.
- (11) The Chief Executive Officer of the Authority may, for stated reasons, revoke or vary a prohibition order made in accordance with this section and the Board shall be notified at the next available meeting of the Board of any such revocation or variation and the reasons therefore.
- (12) The Chief Executive Officer of the Authority shall, in the public interest make such arrangements as he or she considers necessary or appropriate to bring the matter giving rise to a prohibition order to the attention of the public.
- (13) (a) Where a prohibition order has been served and activities are carried on in contravention of the prohibition order, the High Court may, on the application to it in that behalf by the Authority, by order prohibit the continuance of the activities.
- (b) An application to the High Court for an order under this paragraph shall be by motion and the Court, when considering the matter, may make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under this paragraph is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.

## CHAPTER 3

*Amendments of Act of 1962***Amendment of section 2 of Act of 1962**

57. Section 2 of the Act of 1962 is amended by—

- (a) the insertion of the following definitions:

“ ‘Authority’ means the Health Information and Quality Authority;

‘designated person’ means—

- (a) in relation to a hospital, the person designated in that behalf by the hospital concerned to receive and act in accordance with authorisations from family members of deceased persons under section 33F, and
- (b) in relation to a relevant facility, the person designated in that behalf to receive and act in accordance with authorisations from family members of deceased persons under section 33F;

‘Executive’ means the Health Service Executive;

‘healthcare professional’ means—

- (a) a registered medical practitioner,

- (b) a registered nurse or registered midwife within the meaning of section 2(1) of the Nurses and Midwives Act 2011, or
- (c) a member of one or more of the following designated professions within the meaning of section 3 of the Health and Social Care Professionals Act 2005, namely:
  - (i) medical scientist;
  - (ii) psychologist;
  - (iii) social care worker;
  - (iv) social worker;
  - (v) such other designated profession within the meaning of the said section as the Minister considers appropriate and may prescribe by regulations;

‘hospital’ has the same meaning as it has in *section 39* of the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024*;

‘operator’ means, in relation to a relevant facility, the person who has ultimate responsibility for the running of the relevant facility;

‘register of relevant facilities’ shall be construed in accordance with section 33J;

‘relevant facility’ means—

- (a) the Dublin District Mortuary, or
- (b) any other facility (howsoever described), other than a hospital, where post-mortem examinations take place in accordance with this Act and which is specified in the register of relevant facilities as being such place;

‘relevant sections’ means sections 33(2B), 33(2C), 33(2D), 33(3A), 33(3B), 33(3C), 33(3D), 33F, 33G, 33H, 33I, 33J, 33K, 33L, 33M, 33N and 33O;”,

and

- (b) by the substitution of the following definition for the definition of “stillborn child”:

“ ‘stillborn child’ has the same meaning as it has in the Act of 2004;”.

### **Amendment of section 33 of Act of 1962**

**58.** Section 33 of the Act of 1962 is amended—

- (a) by the insertion of the following subsections after subsection (2):

- “(2A) A registered medical practitioner may, when carrying out a post-mortem examination in accordance with subsection (1), be assisted (whether by way of technical or clinical assistance) in carrying out such examination by an appropriately qualified healthcare professional or other person who, in the opinion of the registered medical practitioner carrying out or supervising the examination, is sufficiently qualified or has the relevant training or experience to provide such assistance.
- (2B) A registered medical practitioner may under a direction in subsection (1), for the purposes of the post-mortem examination, remove and retain for such period any material from the body, as appears to the registered medical practitioner to relate to the circumstances of the death, including the cause of death of the deceased person.
- (2C) Where the post-mortem examination has been conducted in a hospital, any material removed from the body under a direction in subsection (1) shall be preserved, stored and recorded in accordance with regulations made in that regard by the Minister for Health under *section 40* of the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024*.
- (2D) Where the post-mortem examination has been conducted in a relevant facility, any material removed from the body under a direction in subsection (1) shall be preserved, stored and recorded, in accordance with regulations made in that regard by the Minister under *section 33I*.”.
- (b) by the insertion of the following subsections after subsection (3):
- “(3A) In providing the information under subsection (3), a coroner shall notify or cause to be notified a family member of the deceased person, the subject of the information, that approval by the family member (in this Act referred to as an ‘authorisation’) will be sought in respect of the final management of certain material of the deceased person.
- (3B) Subsequent to the information being provided to a family member under subsection (3), the coroner shall further notify or cause to be notified the family member concerned that certain material has been retained for the purposes of the post-mortem examination.
- (3C) Where at any time following a post-mortem examination, a coroner on foot of receipt of confirmation from a registered medical practitioner directed to make that examination is satisfied that retention of material from the body of the deceased is no longer necessary, or where the provisions of *section 33(4)* apply, he or she shall notify or cause to be notified a family member of the deceased person of that fact.

- (3D) A notification under subsection (3C) shall inform the family member, the recipient of the notification of the following, namely:
- (a) that the coroner has requested the designated person in the hospital or relevant facility where the post-mortem examination took place to contact the family member;
  - (b) the contact details of the designated person;
  - (c) that the designated person will request an authorisation from the family member for the final management of certain material retained following that examination;
  - (d) the authorisation for final management of material shall provide for—
    - (i) the return of material removed from the body where such return is consistent with guidelines, but shall not include tissue samples held on slides or blocks or trimmings or bodily fluids removed during the post-mortem examination,
    - (ii) the disposal of the material, by the designated person in a hospital or relevant facility, or
    - (iii) the use, by the hospital or relevant facility, of the material to further clinical teaching, medical education or research prior to ultimate disposal.”
- (c) by the insertion of the following subsections after subsection (5):

- “(6) The Minister may prescribe the form of notification under this section.
- (7) In this section, ‘technical or clinical assistance’, in relation to the carrying out of a post-mortem examination, includes the removal by a person providing the assistance, of a part of a body from the deceased adult, child or foetus, the subject of the examination concerned.”.

#### **Amendment of section 33B of Act of 1962**

**59.** Section 33B of the Act of 1962 is amended by the deletion of subsection (1).

#### **Further amendment of Act of 1962**

**60.** The Act of 1962 is amended by the insertion of the following sections after section 33E:

**“Authorisation for final management of material removed from body of deceased person**

**33F.** (1) Where—

- (a) a post-mortem examination of a deceased person has taken place in a hospital or relevant facility, and



- (b) the designated person in the hospital or relevant facility has been requested by or on behalf of the coroner to request an authorisation from a family member of the deceased person, the subject of the post-mortem examination,

the designated person in the hospital or relevant facility where the post-mortem examination took place shall request an authorisation from the family of the deceased person, the subject of the post-mortem examination, for the final management of certain material from the body of the deceased person which was retained following that examination.

- (2) The designated person shall ensure, in so far as practicable, that the authorisation shall be provided in the terms referred to in section 33(3D)(d)(i), (ii) or (iii) in respect of the final management of the material concerned.
- (3) When an authorisation is received by a designated person in respect of the final management of material, he or she shall, as soon as practicable—
- (a) give effect to the authorisation,
- (b) notify the coroner concerned that the authorisation has been so given effect, and
- (c) make this information available to the family member of the deceased should it be so requested by the family member.
- (4) Where no authorisation is received by the designated person under subsection (3) or where efforts to contact family members of the deceased have not proved successful, the designated person shall inform the coroner concerned of that fact and the coroner shall be authorised to direct the final management of the material concerned by the designated person.
- (5) The final management of any material, other than material referred to in section 33(3D)(d)(i), removed from the body of a deceased person shall not be made where the coroner concerned is satisfied that such material may be required for evidential purposes in a relevant legal process and has notified the designated person in that regard.
- (6) The management of any material stored—
- (a) in a hospital shall be carried out in accordance with regulations made in that regard by the Minister for Health under *section 40* of the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024*, or
- (b) in any relevant facility shall be carried out in accordance with regulations made in that regard by the Minister.

**Provisions to apply when no authorisation received for final management of material removed from body of deceased person**

**33G.** In a case to which section 33F(4) applies, the coroner shall direct that the final management of the material concerned be carried out by the designated person, or such other person as appears to the coroner to be appropriate in the hospital or relevant facility, as the case may be, where the material is stored, in accordance with section 33(3D)(d)(ii) or (iii) as is appropriate in the circumstances.

**Provisions to apply when designated person not available or in position to receive or to act on authorisation for final management of material removed from body of deceased person**

**33H.** (1) Where a coroner is notified or otherwise becomes aware that a designated person is not available or not otherwise in a position to receive or act in accordance with an authorisation for the final management of material removed from the body of a deceased person, the coroner shall—

- (a) seek or confirm the authorisation of the family member in respect of the final management of certain material removed from the body of the deceased person, the subject of the authorisation, and
- (b) direct the final management of the material in accordance with the authorisation received.

(2) When the coroner has completed the matters referred to in subsection (1), he or she shall endeavour in so far as is practicable to make this information available to the family member of the deceased should it be so requested.

**Regulations in respect of management of material retained following coronial post-mortem examinations made in relevant facilities**

**33I.** (1) Without prejudice to the generality of section 3, the Minister may make such regulations as he or she considers necessary or expedient for the purpose of proper management in the most respectful and appropriate manner possible of material retained in the course of coronial post-mortem examinations that are made in relevant facilities.

(2) In particular, but without prejudice to the generality of subsection (1), regulations under subsection (1) may provide for any or all of the following matters:

- (a) procedures for the retention, storage and management of material removed from the body as part of the coronial post-mortem examination, where such action is consistent with any guidelines made in that regard;
- (b) the arrangements to be put in place to facilitate receipt of notification of authorisations under section 33F(1), including the designation of persons or classes of persons to whom such

- notifications shall be given and the procedures for the carrying out of authorisations received in that regard;
- (c) the return of any material referred to in paragraph (a) to a family member of the deceased person other than tissue samples held on slides or blocks or trimmings or bodily fluids removed during the examination;
  - (d) the form of notifications under sections 33(3B), 33(3C) and 33(3D);
  - (e) the form of authorisations under 33F;
  - (f) the form of notification of details of relevant facilities under section 33J;
  - (g) any additional information as the Minister considers may reasonably be required for the purposes of the register of relevant facilities;
  - (h) the particulars of notification of incidents to be declared to the Authority;
  - (i) any other matters which are necessary or expedient for the purposes of giving effect to subsection (1).
- (3) Before making regulations under subsection (1), the Minister shall consult such persons as he or she considers appropriate, including all or any of the following:
- (a) a representative of the Coroners Society of Ireland;
  - (b) a pathologist from the Royal College of Physicians of Ireland, Faculty of Pathology;
  - (c) the Chief State Pathologist;
  - (d) the Executive;
  - (e) the Authority;
  - (f) the Minister for Health.

**Register of relevant facilities**

- 33J.** (1) As soon as may be after the commencement of this section, the Minister shall—
- (a) request in writing each coroner who is for the time being holding office to provide the Minister in such form and manner as may be prescribed and within such period as may be prescribed details of any relevant facility where the coroner directs post-mortem examinations to be made in accordance with this Act, and

- (b) establish and maintain in such form as he or she considers appropriate, a register of relevant facilities (in this Act referred to as the ‘register of relevant facilities’) to which the regulations under section 33I shall apply.
- (2) Where a coroner receives a request in writing under subsection (1)(a), the coroner shall comply with that request.
- (3) Notwithstanding the generality of subsection (1)(a), where, at any time, a coroner is of reasonable opinion that a facility (howsoever described) where he or she directs post-mortem examinations to be made in accordance with this Act is a relevant facility, he or she shall notify the Minister in writing of that opinion for the purpose of having that facility registered in the register of relevant facilities.
- (4) The register of relevant facilities shall contain the following information, namely:
- (a) the name of the relevant facility;
  - (b) the location of the relevant facility;
  - (c) the operator of the relevant facility;
  - (d) the chief executive officer (howsoever described) of the relevant facility;
  - (e) the nominated person in relation to the relevant facility;
  - (f) any additional information as the Minister considers may reasonably be required and as may be prescribed under section 33I.
- (5) If a particular entered in the register of relevant facilities is incorrect, the coroner in respect of the relevant facility to which the particular relates shall, as soon as may be after becoming aware of its being incorrect, inform the Minister thereof accordingly.
- (6) The Minister shall, at regular intervals as may be agreed between the Minister and the Authority and, in any event, when a material change is made to the register, provide a copy of the register to the Authority.

**Nominated person**

- 33K.** (1) Subject to subsection (2), a relevant facility at which post-mortem examinations take place shall, as soon as practicable after the commencement of this section and, in any event, not later than 12 weeks after such commencement, nominate in writing at least one suitably qualified person for the purposes of the relevant sections (in this section referred to as a ‘nominated person’).
- (2) A nominated person shall be an employee of the relevant facility concerned and shall be suitably qualified person by reason of his or

her training and experience to discharge the responsibilities of a nominated person.

- (3) A nominated person shall have the following responsibilities, namely:
  - (a) to notify, in accordance with any guidelines, the Authority of the post-mortem examinations that take place in the relevant facility in relation to which he or she is the nominated person.
  - (b) to ensure that an annual report of post-mortem examinations that take place in the relevant facility is compiled and submitted to the Authority;
  - (c) to maintain or cause to be maintained records in accordance with regulations under section 33I;
  - (d) without prejudice to the powers of the Authority under *Part 3* of the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024* and section 8 of the Health Act 2007, to monitor compliance with the relevant sections and any regulations under section 33I and notify the Authority in writing when he or she becomes aware of any breach of a provision of those sections or regulations;
  - (e) to liaise with the Authority from time to time and when requested to do so by the Authority.
- (4) The operator of a relevant facility at which post-mortem examinations take place shall, notwithstanding the nomination by the relevant facility of a nominated person, at all times remain responsible for, and accountable to the Authority in respect of, compliance with regulations under section 33I.

**Authority to monitor compliance with relevant sections – authorised persons etc.**

- 33L.** (1) The Authority shall, pursuant to section 8(1)(p) of the Health Act 2007, monitor compliance with the relevant sections and any regulations made by the Minister under section 33I.
- (2) An authorised person appointed under section 70 of the Health Act 2007 shall be deemed to be an authorised person for the purposes of this section.
  - (3) A relevant facility shall, as soon as practicable after the commencement of section 33K and, in any event, not later than 12 weeks after such commencement, notify the Authority in writing of the following, namely:
    - (a) the name and particulars of the nominated person nominated in that behalf pursuant to section 33K;

- (b) the name and address of the premises at which the post-mortem examinations take place or are intended to take place;
  - (c) the post-mortem examinations which take place or are intended to take place on the premises.
- (4) Where a relevant facility changes in a material way any of the matters notified under subsection (3), the relevant facility shall as soon as possible and, in any event, not later than 28 days after the material changes, inform the Authority in writing and provide it with details of the changes.
- (5) Without prejudice to the generality of subsection (3), the Authority may require the coroner or relevant facility at which post-mortem examinations take place or will take place to provide it within such reasonable period as the Authority may require with any information or statistics the Authority requires in order to determine the level of compliance by the relevant facility with regulations under section 33I.
- (6) Where a person receives a request under subsection (5) from the Authority, he or she shall comply with such request.

#### **Compliance notices**

- 33M.** (1) Where an authorised person is of the opinion that there is non-compliance by a relevant facility with the relevant sections or any regulations made under section 33I, the authorised person may, following consultation with the Chief Executive Officer of the Authority or such other officer of the Authority so designated for that purpose, serve, or cause to be served, on the operator of the relevant facility concerned a notice (in this Act referred to as a ‘compliance notice’) in accordance with this section.
- (2) A compliance notice shall be signed by the authorised person who is issuing the notice or the person referred to in subsection (1) whom he or she consulted with in relation to the notice concerned and shall—
- (a) specify the requirement of the relevant sections or regulations under section 33I with which there has not been compliance,
  - (b) for the purposes of ensuring compliance by the relevant facility concerned, require the operator of the relevant facility by such date as is specified in the notice to do or refrain from doing such act or acts as is or are so specified in the notice, and
  - (c) contain information regarding the bringing of an appeal under section 33N against the notice, including information on the manner in which any such appeal shall be brought.
- (3) A compliance notice shall, unless an appeal is brought under section 33N, come into operation on the expiry of 14 days from the date of service of the notice.

- (4) Where a person on whom a compliance notice has been served fails to comply with the notice at any time on or after the date on which the notice comes into operation, he or she shall be guilty of an offence and shall be liable on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both.
- (5) Summary proceedings for an offence under subsection (4) may be brought and prosecuted by the Authority.

#### **Appeal of compliance notice**

- 33N.** (1) The operator of a relevant facility on whom a compliance notice has been served may within 14 days of service of the compliance notice appeal to the District Court in respect of the notice or any requirement therein.
- (2) Where an appeal is brought under this section, the District Court may—
    - (a) confirm the compliance notice, or
    - (b) direct the authorised person to withdraw the compliance notice concerned.
  - (3) Where the District Court makes an order under subsection (2)(b), the compliance notice shall cease to have effect.
  - (4) Where the District Court confirms a compliance notice, the notice as so confirmed, shall come into operation on the expiry of 14 days of the date of confirmation or such later date as the court may determine.
  - (5) The jurisdiction conferred on the District Court under this section shall be exercised by a judge of that court for the time being assigned to the district court district in which the person on whom the compliance notice is served ordinarily resides or carries on any profession, business or occupation.

#### **Prohibition orders**

- 33O.** (1) Where an authorised person is of the opinion that—
- (a) there is a serious and material non-compliance with a requirement of the relevant sections or any regulations under section 33I, and
  - (b) there is—
    - (i) a need in the public interest to immediately cease any or all of the post-mortem examinations, the subject of the opinion concerned, or
    - (ii) a failure to comply with a compliance notice,
- the authorised person may, with the approval of the Chief Executive Officer of the Authority, or another officer of the Authority designated for that purpose, serve, or arrange to have served, on the operator of

the relevant facility, an order (in this Act referred to as a ‘prohibition order’) in accordance with subsection (2).

- (2) A prohibition order shall be signed by the authorised person issuing it, or the person referred to in subsection (1) who approves the issuing of the prohibition order and shall—
  - (a) state that the authorised person is of the opinion that one or more of the grounds specified in subsection (1) for the serving of a prohibition order exists,
  - (b) specify the particular serious and material non-compliance, public interest need or failure, as the case may be, at issue,
  - (c) where relevant, identify the part or parts of the compliance notice with which there has not been compliance, and
  - (d) as appropriate, direct the operator of the relevant facility served with the order to cease, or arrange for the cessation of, any or all of the post-mortem activities specified in the order concerned.
- (3) The approval referred to in subsection (1) or subsection (6), as the case may be, may be given orally or in writing and if given orally shall be recorded in writing as soon as practicable.
- (4) A prohibition order shall take effect—
  - (a) where the prohibition order so declares, immediately upon receipt of the order by the person on whom it is served, or
  - (b) in any other case—
    - (i) where no appeal is taken against the prohibition order, on the expiration of the period during which such an appeal may be taken or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later, or
    - (ii) where an appeal is taken, on the day immediately following the day on which the prohibition order is confirmed on appeal or withdrawn or the day specified in the prohibition order as the date on which it is to come into effect, whichever is the later.
- (5) The bringing of an appeal against a prohibition order which is to take effect in accordance with subsection (4)(a) shall not have the effect of suspending the operation of the prohibition order, but the appellant may apply to the District Court to have the operation of the prohibition order suspended until the appeal is disposed of and, on such application, the District Court may, if it thinks it proper to do so, direct that the operation of the prohibition order be suspended until the appeal is concluded.
- (6) In the event of non-compliance or delay by the operator of a relevant facility on whom the prohibition order has been served, an authorised



person shall, with the approval of the Chief Executive Officer or another officer designated for that purpose by the Authority, take whatever steps are considered necessary to ensure compliance with the direction given under this section.

- (7) The operator of a relevant facility on whom a prohibition order is served who is aggrieved by a prohibition order may, within the period of 7 days beginning on the day on which the prohibition order is served on him or her, appeal against the order to a judge of the District Court in the district court district in which the prohibition order was served on him or her and, in determining the appeal, the judge may—
  - (a) if he or she is satisfied that in the circumstances of the case it is reasonable to do so, confirm the prohibition order, with or without modification, or
  - (b) where he or she is not so satisfied of the matters referred to in paragraph (a), allow the appeal and cancel the prohibition order.
- (8) Where on the hearing of an appeal under this subsection a prohibition order is confirmed, notwithstanding subsection (5), the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition order for such period as in the circumstances of the case the judge considers appropriate.
- (9) A person who appeals against a prohibition order or who applies for a direction suspending the application of the prohibition order under subsection (5) shall at the same time notify the Authority of the appeal or the application and the grounds for the appeal or the application and the Authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or the application.
- (10) The Board of the Authority shall be notified at the next available meeting of the Board of the service of a prohibition order.
- (11) The Chief Executive Officer of the Authority may, for stated reasons, revoke or vary a prohibition order made in accordance with this section and the Board shall be notified at the next available meeting of the Board of any such revocation or variation and the reasons therefore.
- (12) The Chief Executive Officer of the Authority shall, in the public interest make such arrangements as he or she considers necessary or appropriate to bring the matter giving rise to a prohibition order to the attention of the public.
- (13) (a) Where a prohibition order has been served and activities are carried on in contravention of the prohibition order, the High Court may, on the application to it in that behalf by the Authority, by order prohibit the continuance of the activities.

- (b) An application to the High Court for an order under this paragraph shall be by motion and the Court, when considering the matter, may make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under this paragraph is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.”.

## PART 4

### ANATOMICAL EXAMINATION

#### **Definitions (*Part 4*)**

**61.** In this Part—

“anatomical consent” shall be construed in accordance with *section 63*;

“anatomical examination” means the use of a body, or any part of a body, for the purposes of the study and practice of the science of anatomy;

“anatomical specimen” means a body (including separated parts of such a body)—

- (a) intended to be used for anatomical examination in accordance with this Part, or
- (b) which is being used for anatomical examination in accordance with this Part;

“applicant institution” has the meaning assigned to it by *section 68*;

“authorised officer” means a person appointed under *section 79*;

“body” means the body of a deceased person;

“licensed institution” means an institution licensed by the Medical Council under *section 68* in respect of the carrying out of anatomical examinations;

“relevant institution” means any one of the following:

- (a) the college of the Holy and Undivided Trinity of Queen Elizabeth near Dublin established by charter dated the 3rd day of March 1592 and shall be held to include the University of Dublin;
- (b) Royal College of Surgeons in Ireland;
- (c) University College Dublin;
- (d) University College Cork;
- (e) University of Galway;

“responsible person” has the meaning assigned to it by *section 65*.

**Application of Part**

62. This Part shall not apply to a body or a part of a body that was donated pursuant to the provisions of the Anatomy Act 1832 or imported by a relevant institution for the purposes of anatomical examination before the commencement of this section.

**Consent to donate body for anatomical examination**

63. (1) Subject to *subsection (6)*, an anatomical examination shall not be carried out on a body at a licensed institution unless the institution is in receipt of a consent in respect of that body, given in accordance with this section or *section 67*, as the case may be.
- (2) A person who has attained the age of 18 years may give his or her consent (in this Part referred to as an “anatomical consent”) to the donation of his or her body to a licensed institution for purposes of anatomical examination.
- (3) Where a person is considering whether to provide an anatomical consent, the following information shall be provided to him or her by or on behalf of a licensed institution, namely:
- (a) the nature of the activities for which a body may be used;
  - (b) the period of time in respect of which the body (or parts of the body), the subject of the consent may be retained;
  - (c) information relating to any loan or transfer of the body;
  - (d) information relating to the disposal of the body (including information relating to the repatriation of a body which may be exported);
  - (e) without prejudice to *paragraphs (a) to (d)*, any other information for the time being specified by the Medical Council as being necessary information to be given to a person who is considering providing his or her consent under this section.
- (4) An anatomical consent shall be given in the form for the time being standing specified by the Medical Council for that purpose and without prejudice to the generality of the foregoing shall—
- (a) be in writing,
  - (b) be signed by the person in the presence of at least one witness who shall attest the signature,
  - (c) include a confirmation by the person concerned that he or she has been furnished with, and understands, the information referred to in *paragraphs (a) to (e)* of *subsection (3)*,
  - (d) indicate whether the person consents to his or her body being loaned or transferred in accordance with any authorisation given in that behalf to the institution by the Medical Council, and
  - (e) specify the period of time that the person consents to his or her body being used for the purposes of anatomical examination.

- (5) An anatomical consent given by a person may be revoked or amended by the person at any time before his or her death in like manner and conditions by notifying in writing, in the form for the time being standing specified by the Medical Council for that purpose, the licensed institution in respect of which the anatomical consent relates, furnishing details of the revocation of, or amendment to, the consent, as the case may be.
- (6) A person shall not be entitled to financial or other like reward for the giving of his or her consent under this section other than financial assistance provided after the person's death in respect of—
- (a) the costs of the transportation of the body to the licensed institution in accordance with the procedures in place in the licensed institution,
  - (b) the provision of a coffin and transportation of the body to the place of burial or cremation, the subject of the consent, or
  - (c) without prejudice to the generality of *paragraph (b)*, reasonable costs of the transfer or disposal of the person's body in accordance with the consent given by the person,
- and, any financial or other like reward given in respect of an anatomical consent shall render the consent null and void.
- (7) Subject to any provision to the contrary provided in an anatomical consent, a licensed institution may bury (whether in a place owned by or under the control of, the licensed institution concerned or in a place designated by the institution for that purpose) the remains, or the cremated remains as the case may be, of a body the subject of a consent.
- (8) An anatomical consent given by a person under this section is given for the purposes and only the purposes of anatomical examination.
- (9) A copy of the anatomical consent provided under this section shall be—
- (a) furnished to the person giving his or her consent, and
  - (b) retained at the licensed institution which received the body.
- (10) A person who contravenes *subsection (1)* shall be guilty of an offence.

**Medical certificate of cause of death must be signed before anatomical examination can take place**

64. (1) Where a person has consented under *section 63* to the use of his or her body after death for the purposes of anatomical examination, the donor's body may be brought to a licensed institution and embalmed or otherwise preserved before the death has been duly registered in the register of deaths by an tArd-Chláraitheoir.
- (2) No anatomical examination shall take place until a medical certificate of the cause of death has been signed and furnished to the licensed institution in respect of the body.

- (3) A copy of the medical certificate of the cause of death shall be kept at the licensed institution which received the body for such period as shall be specified in a code of practice under *section 81* which period shall not be less than 5 years.

#### **Practice of anatomical examination**

- 65.** (1) A person who is named on a licence (in this Part referred to as “responsible person”) granted by the Medical Council to a licensed institution or a person who is authorised by, or under the direction of, a responsible person may, in accordance with this Part, carry out or participate in anatomical examinations.
- (2) A person shall not carry out anatomical examinations otherwise than in a licensed institution.
- (3) Where a donor donates his or her body to a licensed institution, the institution shall be responsible for the donor’s body or part or parts of that body, as the case may be, from the time that the institution accepts the donation for anatomical examination until such time as the body so donated is buried, cremated, disposed of or returned to the donor’s family as may be appropriate.
- (4) A person who contravenes *subsection (2)* shall be guilty of an offence.

#### **Loan or transfer of anatomical specimens for purposes of anatomical examination**

- 66.** (1) A licensed institution, if it is in receipt of a prior authorisation given to it by the Medical Council, may by agreement loan or transfer an anatomical specimen to another licensed institution or to a like institution in Northern Ireland for the purposes of anatomical examination.
- (2) In making an application to the Medical Council for an authorisation, the licensed institution shall specify in writing—
- (a) the anatomical specimens that are the subject of the loan or transfer, as the case may be,
- (b) the purpose for which the loan or transfer, as the case may be, is being made,
- (c) in the case of a loan, the duration of the loan period, and
- (d) the name and location of the institution where the anatomical specimens will be held.
- (3) An anatomical specimen that is on loan under *subsection (1)* shall remain the responsibility of the lending institution.
- (4) An anatomical specimen that is transferred to another licensed institution or to a like institution in Northern Ireland, as the case may be, shall be the responsibility of—
- (a) in the case of a transfer to another licensed institution, that other licensed institution, or
- (b) in the case of transfer to a like institution in Northern Ireland in accordance with this section, the institution to which it is transferred.

- (5) It shall be for both licensed institution which loans or transfers, as the case may be, an anatomical specimen and the licensed institution which receives an anatomical specimen on loan or transfer, as the case be, to show if so requested in writing by the Medical Council that the loan or transfer is made in accordance with this Part and any anatomical consent given by the donor in respect of the specimen concerned.
- (6) All records (which shall include a copy of the records referred to in *sections 64(3), 67 and 76*) relating to an anatomical specimen shall be transferred from the licensed institution which transfers, to the licensed institution or like institution in Northern Ireland, as the case may be, receiving the specimen the subject of the transfer.
- (7) A licensed institution which loans or transfers an anatomical specimen under this section shall retain copies of the records transferred under *subsection (6)* for such period as shall be specified in a code of practice under *section 81*, which period shall not be less than 5 years.
- (8) A licensed institution receiving an anatomical specimen shall be responsible—
  - (a) in the case of a loan, for the return of that specimen to the licensed institution who made the loan, or
  - (b) in the case of a transfer, for the disposal of that anatomical specimen in accordance with consent provided under *section 63*.

#### **Importation of anatomical specimens for anatomical examination**

67. (1) A licensed institution may, if it is in receipt of prior authorisation issued to it in that behalf by the Medical Council, import anatomical specimens for anatomical examination.
- (2) In making an application to the Medical Council for an authorisation, the licensed institution shall specify in writing—
    - (a) the anatomical specimens that are the subject of the proposed importation,
    - (b) the purpose for which the proposed importation is being made,
    - (c) in the case of a loan, the duration of the loan period, and
    - (d) the location at which the anatomical specimens will be held.
  - (3) An anatomical specimen shall be obtained, transported, used and disposed of by a licensed institution in accordance with any consent given by the donor in respect of the body concerned.
  - (4) It shall be for the licensed institution to satisfy itself and to show, if so requested in writing by the Medical Council, that the anatomical specimen has been obtained, transported, used and disposed of by the institution concerned in accordance with any consent given by the donor of the specimen concerned.
  - (5) Where an anatomical specimen is imported into the State by a licensed institution for the purposes of anatomical examination, it shall be for the licensed institution to show, if so requested in writing by the Medical Council, that the institution complied

with the legal requirements in the country from which the anatomical specimen has been imported.

- (6) Without prejudice to the generality of *subsection (4)*, evidence of compliance referred to in that subsection may comprise of evidence to show that the anatomical specimens have been imported in accordance with rules (howsoever described) relating to anatomical examination and donation of human tissue where such rules are, in the view of the Medical Council, equivalent to the provisions of this Part.

### **Licensed institutions**

**68.** (1) Where, immediately before the commencement of this section, a licence to carry out anatomical examinations is standing issued and for the time being in force under the Anatomy Act 1832 to a person in a relevant institution and—

- (a) the relevant institution wishes to continue to carry on anatomical examinations after that commencement, and
- (b) the person named on the licence on behalf of the relevant institution or nominated for that purpose by the relevant institution and duly approved in that behalf by the Medical Council is and will for the time being remain in that capacity at the relevant institution,

the institution shall, within 12 weeks of such commencement, apply to the Medical Council for a licence to carry out anatomical examinations under this Part and, where that relevant institution makes such application, the institution may continue to carry on with such examinations in accordance with the licence or licences, as the case may be, for the time being in force on the date of such application pending a decision by the Medical Council on that application.

- (2) Where an institution wishes to carry out anatomical examinations, the institution (in this section referred to as an “applicant institution”) shall apply to the Medical Council for a licence authorising the institution to carry out anatomical examinations.
- (3) An application under this section shall—
- (a) be in such form and made in such manner as may be specified by the Medical Council,
  - (b) specify the name and address of the applicant institution,
  - (c) specify the name of the proposed responsible person and the address of his or her principal office or place of business,
  - (d) specify the qualifications of the proposed responsible person,
  - (e) provide details of the facilities of the applicant institution with respect to the activities, the subject of the application,
  - (f) specify the premises at which it is proposed to undertake anatomical examinations,

- (g) provide such other information, including information regarding the governance of the applicant institution as the Medical Council may specify, and
  - (h) be accompanied by the fee as determined by the Medical Council under *subsection (13)*.
- (4) Upon receipt of an application for a licence under this section, the Medical Council shall—
- (a) in the case of an applicant institution in respect of which more than 2 years has elapsed since an inspection was last carried out on the institution,
  - (b) where the applicant institution is making an application to become a licensed institution for the first time, or
  - (c) where the Medical Council with good reason considers it appropriate to do so, cause an inspection to be undertaken of one or more premises which is or are identified in the application as being the premises at which anatomical examinations will be undertaken by the licensed institution if the licence is granted and prepare a written report following such inspection.
- (5) Where having considered the application received in accordance with this section, the written report prepared under *subsection (4)* (where relevant) and the matters specified in *subsection (6)*, the Medical Council may—
- (a) issue a licence to an institution,
  - (b) issue the licence subject to such conditions as the Medical Council may specify, or
  - (c) refuse to issue the licence.
- (6) The Medical Council shall, in determining a licence application under this section have regard to any codes of practice or guidance issued in respect of anatomical examinations by the Council and any guidelines.
- (7) The Medical Council shall not issue a licence to an institution to carry out anatomical examinations unless it is satisfied that such anatomical examinations shall be carried out by that institution in accordance with the licence and this Part.
- (8) A licence shall—
- (a) state the name and address of the institution, the holder of the licence concerned,
  - (b) specify the premises at which anatomical examinations will be undertaken,
  - (c) record on the licence the name and business address of the proposed responsible person in respect of the institution concerned,
  - (d) specify the date from which the licence shall have effect, and
  - (e) specify the conditions attached to the licence, if any.
- (9) Where the Medical Council proposes to refuse to issue a licence under *subsection (5)(c)*, it shall notify the applicant institution in writing of the proposed



refusal and the reasons for such proposed refusal, and notify the applicant institution that the institution may make representations in writing to the Council within 21 days of the date of such notice.

- (10) An applicant institution which receives a notification under *subsection (9)* may within 21 days of the notice make representations in writing in respect of the proposal by the Medical Council to refuse the application for a licence.
- (11) Where a notification has been given under *subsection (9)*, the Medical Council shall within 21 days of receipt of any representations consider the representations made to it and shall not issue a final decision until—
  - (a) it has considered the representations, if any, made by the applicant institution in accordance with the notification, or
  - (b) the period referred to in *subsection (10)* has elapsed and no representations are made by the applicant institution concerned.
- (12) Where the Medical Council, having considered the representations (if any) made to it in that behalf under *subsection (10)*, decides to refuse an application for a licence, it shall notify the applicant institution in writing—
  - (a) of the decision and the reasons for it, and
  - (b) that the applicant may appeal the refusal under *section 74*.
- (13) Without prejudice to the generality of *section 36(j)* of the Act of 2007, the Medical Council may, with the consent of the Minister, charge such fee as the Council may determine, to accompany an application made under *subsection (1)* or *(2)* and different fees may be determined and charged for different classes of application.

#### **Notification of grant of licence to institution**

69. The Medical Council shall, as soon as is practicable after it issues a licence under *section 68*, publish a notice in whatever form it considers appropriate stating, at a minimum—
  - (a) the name and address of the institution, the holder of the licence and the name of the responsible person in respect of the institution, and
  - (b) the physical address or addresses of the premises or locations at which anatomical examinations, the subject of the licence may be undertaken and (if applicable) the electronic address or addresses of such premises or locations as the case may be.

#### **Material amendment of licence**

70. A licensed institution that wishes for its licence to be amended in a material way shall make a licence application for such amendment and, in the case of such application, *section 68* and the other provisions of this Part applicable to a licence application shall, with all necessary modifications, apply accordingly.

**Removal, variation or addition of conditions**

71. (1) Without prejudice to the generality of *section 68(5)(b)* the Medical Council, where it considers it necessary to do so may vary a licence issued under *section 68*, including by way of varying a condition, imposing a condition, including an additional condition, or removing a condition attached to it.
- (2) Where the Medical Council proposes to vary a licence under *subsection (1)*, it shall notify the licensed institution in writing of the proposal and any such notification shall—
- (a) specify the condition to the licence which it proposes—
    - (i) to remove or vary and provide details of the proposed variation and the reasons for it, or
    - (ii) to impose on the licence and the reasons for it,
  - (b) specify the date from which the condition shall apply, which date shall not be less than 21 days from the date on which the notice is served, and
  - (c) inform the licensed institution that it may make representations in writing to the Council within 21 days of the date of receipt of such notice.
- (3) A licensed institution which receives notification under *subsection (2)* may, within 21 days of the receipt of the notification, make representations in writing in respect of the proposal by the Medical Council to remove, vary or impose a condition on the licence.
- (4) Where a notification has been given under *subsection (2)*, the Medical Council shall, within 21 days of receipt of any representations, consider the representations made to it and shall not issue a final decision regarding its proposal until—
- (a) it has considered the representations, if any, made by the licensed institution in accordance with the notification, or
  - (b) the period referred to in *subsection (2)* has elapsed and no representations are made by the institution.
- (5) Where the Medical Council, having considered within 21 days the representations (if any) made to it in that behalf under *subsection (3)*, decides to remove, vary or impose a condition to a licence, it shall notify the licensed institution in writing—
- (a) of the decision and the reasons for it, and
  - (b) that the institution may appeal the decision under *section 74*.

**Suspension and revocation of licences**

72. (1) Subject to *section 73*, the Medical Council may suspend or revoke a licence for any of the following reasons:
- (a) the licensed institution has or is undertaking anatomical examinations—

- (i) on donated bodies in contravention of the anatomical consents given in respect of those bodies, or
  - (ii) otherwise than in accordance with the provisions of *section 63*;
  - (b) the licensed institution contravened a condition imposed under *section 68* or *71*, as the case may be, on the licence issued to it under *section 68*;
  - (c) that following an inspection by the Medical Council and pursuant to the issuing by it of a compliance notice under *section 82*, the practices at the licensed institution as regards storage, access to or use and treatment (including the treatment with dignity and respect) of anatomical specimens are such that anatomical examination cannot in the opinion of the Medical Council be carried out in accordance with this Part by the licensed institution;
  - (d) the information provided by the licensed institution when applying for a licence under *section 68* or making representations under *section 71* was false or incomplete in any material aspect;
  - (e) the licensed institution is not carrying out, or has informed the Council by a notice in writing that it no longer intends to carry out, the anatomical examination to which the licence relates;
  - (f) the licensed institution does not have the staff, premises, equipment or facilities necessary for carrying out the anatomical examination to which the licence relates.
- (2) Subject to *section 73*, where the Medical Council proposes to suspend or revoke a licence under *subsection (1)*, it shall—
- (a) notify the licensed institution in writing of the proposal and the reasons for the proposal, and
  - (b) inform the licensed institution, the subject of the proposal, that the institution may make representations to the Medical Council not later than 21 days or such further period as the Medical Council allows from the date of the service of the notification and that any such representations shall be considered by the Medical Council.
- (3) A licensed institution which receives a notification under *subsection (2)* may within 21 days of the notification make representations in writing in respect of the proposal.
- (4) Where a notification has been given under *subsection (2)*, the Medical Council shall within 21 days of any representations made to it consider the representations made to it and shall not issue a final decision until—
- (a) it has considered the representations, if any, made by the licensed institution in accordance with the notification, or
  - (b) the period referred to in *subsection (3)* has elapsed and no representations are made by the licensed institution concerned.

- (5) Where the Medical Council, having, within 21 days, considered any representations made by or on behalf of a licensed institution under *subsection (3)*, decides to suspend or revoke a licence, it shall notify the licensed institution in writing of the decision, stating—
- (a) the reasons on which the decision is based,
  - (b) the date on which the suspension or revocation, as the case may be, shall take effect,
  - (c) in the case of a licence which is to be suspended, the period for which it is to be suspended, and
  - (d) that the institution may within 21 days of the decision appeal the decision under *section 74*.
- (6) Where the Medical Council suspends a licence under *subsection (5)*, the Medical Council may, if where it considers it necessary in all the circumstance to do so, extend the period of suspension and where it proposes to do so, *subsection (2)* shall with all necessary modifications apply to the proposal to extend the suspension as it applies to the proposal to suspend a licence.
- (7) Where the Medical Council decides to suspend or revoke a licence under *subsection (5)*—
- (a) the decision takes effect, where no appeal is made within the period referred to in *subsection (5)(d)*, upon the expiration of that period, and
  - (b) in the event of an appeal against the decision being made within that period, the decision stands suspended until the appeal is determined or withdrawn.

### **Medical Council may suspend licence without notice in certain circumstances**

73. (1) Where the Medical Council considers that due to the manner in which anatomical specimens are stored and treated in a licensed institution—
- (a) there is a serious and immediate risk to the life, health or welfare of the staff or students at the licensed institution or to the public, or
  - (b) the licensed institution is failing to treat the anatomical specimens held at its institution with dignity and respect,
- the Medical Council may, without giving notice under *section 72*, suspend the licence for a period not exceeding 21 days and any such suspension shall have effect for a period not exceeding 21 days as shall be specified in a notice in writing served on the licensed institution concerned and shall cease to have effect—
- (i) subject to *subparagraphs (ii) and (iii)*, on the expiry of the date specified in the notice,
  - (ii) in a case which falls to be determined by the Medical Council under *subsection (2)* before the date specified in the notice, on the determination of the Medical Council under *subsection (2)*, or

- (iii) in a case where the licensed institution concerned, the subject matter of the suspension makes, within the period specified in the notice, an application to the High Court under *subsection (3)*, the determination of the High Court.
- (2) Where the Medical Council decides to suspend a licence under *subsection (1)*, the Council shall, as soon as may be, notify in writing the licensed institution—
  - (a) of the decision and the reasons for it,
  - (b) the period for which the suspension shall have effect and the date on which it shall come into operation, and
  - (c) that the institution may on notice make an application in a summary manner to the High Court for consideration and determination by the court of the suspension of the licence concerned.
- (3) A licensed institution which is aggrieved by a decision of the Medical Council under *subsection (1)* may make an application in a summary manner to the High Court for consideration and determination by the court of the decision of the Medical Council.
- (4) The High Court may, on the hearing of an application under *subsection (3)* by a person, consider any evidence adduced or argument made, whether adduced or made to the Council and may—
  - (a) either—
    - (i) confirm the decision that is the subject of the application, or
    - (ii) cancel that decision and replace it with such other decision as the High Court considers appropriate,and
  - (b) give the Medical Council such direction as the High Court considers appropriate and direct how the costs of the application are to be borne.
- (5) An appeal shall lie from a decision of the High Court in respect of an appeal under this section to the Court of Appeal on a point of law only.

**Appeal from decision (other than decision under *section 73*) of Medical Council**

- 74.** (1) A person who is aggrieved by a final decision under *section 68(12)*, *71(5)* or *72(5)* may, not later than 21 days after the person received notice of the decision, appeal to the High Court against the decision.
- (2) The High Court may, on the hearing of an appeal under *subsection (1)* by a person, consider any evidence adduced or argument made, whether adduced or made to the Council.
  - (3) The High Court may, on the hearing of an appeal under *subsection (1)* by a person—
    - (a) either—
      - (i) confirm the decision, the subject of the appeal, or

- (ii) cancel that decision and replace it with such other decision as the High Court considers appropriate,  
and
  - (b) give the Medical Council such direction as the High Court considers appropriate and direct how the costs of the appeal are to be borne.
- (4) An appeal shall lie from a decision of the High Court in respect of an appeal under this section to the Court of Appeal on a point of law only.

### **Responsible persons**

75. (1) Subject to *subsection (7)*, a licensed institution shall, as soon as may be after the commencement of this section and in any event not later than 12 weeks after such commencement, designate at least one appropriately qualified person as a responsible person for the purposes of this Part.
- (2) Without prejudice to the generality of *subsection (1)*, a responsible person shall have the following functions, namely:
- (a) to conduct and direct anatomical examinations at the licensed institution;
  - (b) to make applications to the Medical Council on behalf of the institution for authorisation for the institution to loan, transfer or import anatomical specimens for the purposes of anatomical examination;
  - (c) to maintain or cause to be maintained the records referred to in *section 76*;
  - (d) to undertake duties in respect of the annual return by the licensed institution of its annual report to the Medical Council in such form and manner as is specified by the Medical Council;
  - (e) to liaise with the Medical Council, as required by the licensed institution or the Medical Council.
- (3) The responsible person shall be specified on the licence given by the Medical Council under *section 68*.
- (4) A responsible person may delegate any of the functions specified in *subsection (2)* to other persons each of whom are suitably qualified by training and experience to perform such functions.
- (5) Where a responsible person delegates or proposes to delegate functions under *subsection (4)*, he or she shall ensure that there is in place appropriate training of such persons to enable the delegation of functions and to ensure accountability for the performance of those functions.
- (6) Where a licensed institution proposes to designate, on a temporary or permanent basis, a responsible person other than the responsible person specified in the licence issued to the institution under *section 68*, the licensed institution shall, as soon as may be, provide to the Medical Council for approval—

- (a) the name of the proposed responsible person,
  - (b) his or her qualifications, and
  - (c) the date when the designation shall take effect in respect of the person.
- (7) A responsible person shall, notwithstanding any delegations made by him or her in accordance with this section, at all times remain accountable to the Medical Council for the performance of the function so delegated.
- (8) A responsible person may revoke a delegation made under *subsection (4)*.
- (9) In this section, “an appropriately qualified person” means a person who has such relevant experience, training or expertise as is appropriate having regard to—
- (a) the responsibilities of a responsible person under this Part, and
  - (b) any code of practice for this time being in force in respect of anatomical examinations.

**Records to be kept in relation to donated anatomical specimens**

76. (1) A responsible person shall cause to be maintained in writing or such other form as he or she considers appropriate, or the Medical Council may from time to time specify, a record (in this section referred to as “the record”) in respect of the bodies received by the licensed institution for purposes of anatomical examination at the institution.
- (2) Without prejudice to the generality of *subsection (1)*, the following documents relating to a body received by a licensed institution shall be retained as part of the record:
- (a) a copy of the anatomical consent;
  - (b) a copy of the medical certificate of the cause of death.
- (3) The record shall be—
- (a) maintained in a secure and permanent form, and
  - (b) made available for inspection by the Medical Council or its officers duly authorised as authorised officers.
- (4) Where an anatomical specimen is loaned or transferred to another licensed institution or a like institution outside the State, a copy of the record shall be transferred with the specimen and retained by each of the other institutions where that specimen is loaned or transferred, however a copy of the records shall also be retained by the responsible person at the licensed institution which first received such specimen for anatomical examination.
- (5) Where an anatomical specimen is disposed of by a licensed institution, the records in respect of the specimen shall be kept and maintained in accordance with law.
- (6) The responsible person shall prepare and maintain a written statement specifying the policies and procedures in place in the licensed institution to ensure that—

- (a) there is in place in the licensed institution—
    - (i) a record management system sufficient to ensure data protection and confidentiality, and
    - (ii) a documented internal audit system, with an appropriate schedule and accountability,and
  - (b) members of staff of the licensed institution are appropriately qualified and trained in respect of the duties to which they are assigned or delegated as the case may be.
- (7) A copy of the written statement referred to in *subsection (6)* shall be made available for inspection by the Medical Council or its officers duly authorised as authorised officers.

**Transfer of functions from inspectors of places in State where anatomy is carried on under and in accordance with Anatomy Act 1832 to Medical Council**

77. (1) All functions that, immediately before the commencement of this section, were vested in the inspectors of places in the State where anatomical examination is carried on under and in accordance with the Anatomy Act 1832 are transferred to the Medical Council.
- (2) Without prejudice to the generality of *subsection (1)* and *(3)*, the Medical Council shall have the following functions, namely:
- (a) to undertake or cause to be undertaken, inspections of, and provide or cause to be provided, reports on, premises identified in applications made by applicant institutions to become licensed institutions under *section 68*;
  - (b) without prejudice to the generality of *paragraph (a)*, to conduct inspections not less than once every 3 years of all licensed institutions at which anatomical examinations are undertaken;
  - (c) to monitor compliance by licensed institutions with—
    - (i) the provisions of this Part,
    - (ii) any conditions which have been placed on any licence issued to a licensed institution under this Part, and
    - (iii) any codes of practice for the time being in force in respect of anatomical examination;
  - (d) without prejudice to *sections 68* and *82*, to request an applicant institution or a licensed institution to provide to the Medical Council as soon as it is practicable after receipt of such request, such information as the Medical Council may reasonably require for the purposes of this section and is so specified in its request;



- (e) do such other things as are reasonably necessary or expedient for the purposes of monitoring compliance with this Part;
  - (f) appoint one or more authorised officers to undertake any of the functions referred to in *paragraphs (a) to (e)* of this subsection;
  - (g) make reports to the Minister on an annual basis or whenever requested to do so, in respect of inspections undertaken under this section;
  - (h) of its own motion or at the request of the Minister, to advise the Minister on any matter related to anatomical examination;
  - (i) at the request of the Minister and as soon as it is practicable after receipt of such request, to provide the Minister with such information as the Minister specifies in his or her request.
- (3) The Medical Council shall have all such powers as are necessary or expedient for the performance of its functions under this Part.
- (4) Anything commenced and not completed before the commencement of this section by or under the authority of the Inspector of Anatomy may, be carried on or completed on or after that date by the Medical Council.

#### **Requests by Medical Council for information**

78. Without prejudice to *section 68*, where the Medical Council requests an applicant institution or a licensed institution, as the case may be, to provide to the Medical Council as soon as it is practicable after receipt of such request, such information as the Medical Council may reasonably require for the purposes of this section and is so specified in its request, the applicant institution or the licensed institution, as the case may be, shall comply with that request.

#### **Authorised officers for purposes of Part 4**

79. (1) The Medical Council may appoint one or more persons as the Council sees fit to be authorised officers for the purposes of this Part.
- (2) Each authorised officer shall be furnished with a warrant of his or her appointment and, when exercising a power conferred by this Part shall, if requested by any person affected thereby, produce such warrant of appointment to that person for inspection.
- (3) An appointment under this section shall cease—
- (a) if the Medical Council revokes the appointment,
  - (b) if the appointment is for a fixed period, on the expiry of that period, or
  - (c) in the case of a person who is a member of the staff of the Medical Council as the case may be, if the person ceases to be a member of the staff.

**Powers of authorised officers (Part 4)**

- 80.** (1) For the purposes of this Part, an authorised officer may exercise any of the following powers:
- (a) enter (if necessary, by use of reasonable force) and inspect, at any reasonable time, any premises (other than a dwelling)—
    - (i) specified in a licence issued under this Part,
    - (ii) not specified in a licence but at which he or she has reasonable grounds for believing that anatomical examinations are being undertaken, or
    - (iii) at which he or she has reasonable grounds for believing that documents or records relating to anatomical examinations are kept;
  - (b) require any person on the premises referred to in *paragraph (a)* to produce any documents or records relating to anatomical examinations;
  - (c) secure for inspection—
    - (i) any documents or records relating to anatomical examinations, or
    - (ii) any premises (or part thereof) in which documents or records relating to anatomical examinations are kept;
  - (d) take samples, carry out, or have carried out, such tests, examinations, analyses, inspections or checks of any or all of the following as he or she considers reasonably necessary for the purposes of this Part:
    - (i) the premises;
    - (ii) anything at the premises;
    - (iii) notwithstanding the generality of *subparagraph (ii)*, any equipment, machinery or plant at the premises;
  - (e) require any person at the premises or the owner or person in charge of the premises and any person employed there to give 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 the person's power or procurement, as the authorised officer may reasonably require for the purposes of this Part.
- (2) An authorised officer shall not enter a dwelling, other than—
- (a) with the consent of the occupier, or
  - (b) pursuant to a warrant under *subsection (3)*.
- (3) Upon the sworn information of an authorised officer, a judge of the District Court may, for the purposes of enabling an authorised officer to carry out an inspection under *subsection (1)*, issue a warrant authorising a named authorised officer, accompanied by such other authorised officers or members of the Garda Síochána as may be necessary, at any time or times, before the expiration of one month from the

date of issue of the warrant, to enter (if necessary by use of reasonable force) the dwelling and perform the functions of an authorised officer under *subsection (1)*.

- (4) A person shall be guilty of an offence if he or she—
- (a) obstructs or interferes with an authorised officer or a member of the Garda Síochána in the course of exercising a power conferred on him or her by this Part or a warrant under *subsection (3)*, or impedes the exercise by the person or member, as the case may be, of such power, or
  - (b) fails or refuses to comply with a request or requirement of, or to answer a question asked by, an authorised officer or member pursuant to this section, or in purported compliance with such request or requirement or in answer to such question, give information to an authorised officer or member that he or she knows to be false or misleading in a material particular.
- (5) A person who is guilty of an offence under *paragraph (a)* or *(b)* of *subsection (4)* shall be liable on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both.
- (6) Where an authorised officer believes, upon reasonable grounds, that a person has committed an offence under this Part, the authorised officer may require the person to provide him or her with his or her name and the address at which that person ordinarily resides, and such person shall comply with that requirement.

### **Codes of practice (anatomical examination)**

- 81.** (1) Subject to *subsection (2)*, the Medical Council—
- (a) may, and, at the request of the Minister, shall prepare and publish a code of practice for the purpose of setting standards relating to the undertaking of anatomical examinations and any code of practice shall specify the period for which records shall be retained, which period shall not be less than 5 years, and
  - (b) may, if it thinks appropriate to do so, approve any other code of practice relating to the undertaking of anatomical examinations.
- (2) Before publishing or approving of a code of practice under *subsection (1)*, the Medical Council—
- (a) shall publish in such manner as the Council considers appropriate a draft of the code and shall allow persons 30 days from the date of publication of the draft code within which to make representations in writing to the Medical Council in relation to the draft code or such further period, not exceeding 30 days, as the Medical Council in its absolute discretion thinks fit, and
  - (b) following consultation and, where relevant, having considered the representations (if any) made, shall submit the draft code to the Minister for his or her consent to its publication or approval.
- (3) The Minister may—

- (a) consent to the publication or approval of, as the case may be, a code of practice under this section with or without modification, or
  - (b) refuse to consent to publication or approval of such a code of practice.
- (4) Where the Medical Council publishes or approves of a code of practice under this section, the Minister shall cause a notice to that effect to be published in *Iris Oifigiúil*—
- (a) identifying or specifying the code, and
  - (b) specifying the date from which the code shall have effect.
- (5) The Medical Council may, with the consent of the Minister but subject to *subsection (6)*—
- (a) amend or revoke a code of practice published under this section, or
  - (b) withdraw its approval of any code of practice approved of under this section.
- (6) *Subsection (2)* shall, with all necessary modifications, apply to a code of practice that the Medical Council proposes to amend or revoke, or withdraw its approval of, under *subsection (5)* as *subsection (2)* applies to a code of practice that the Medical Council proposes to publish or approve of under this section.
- (7) Where the Medical Council amends or revokes, or withdraws its approval of, a code of practice published or approved of under this section, the Minister shall cause a notice to that effect to be published in *Iris Oifigiúil*—
- (a) identifying or specifying the code to which the amendment, revocation, or withdrawal, as the case may be, relates and, if applicable, particulars of the amendment, and
  - (b) specifying the date from which the amendment, revocation, or withdrawal, as the case may be, shall have effect.
- (8) The Medical Council shall cause to be published in such form as it considers appropriate a copy of each code of practice published or approved of under this section, as the code is in force from time to time, on and from the date on which the code has effect.
- (9) A document bearing the seal of the Medical Council and purporting to be a code of practice published or approved under this section or, where such a code has been amended under *subsection (7)*, the code as so amended shall be admissible in evidence in any proceedings under this Act or before a court or tribunal.
- (10) In this section, “code of practice” includes part of a code of practice.

**Compliance notices (anatomical examination)**

- 82.** (1) Where the Medical Council is of the opinion that a person has contravened or is contravening—
- (a) the provisions of this Part,

- (b) any conditions which have been placed on any licence issued to an institution under this Part, or
  - (c) any codes of practice for the time being in force in respect of anatomical examination,
- the Medical Council may serve a compliance notice on the person.
- (2) Before serving a compliance notice on a person under *subsection (1)*, the Medical Council shall give the person notice (in this section referred to as “advance notice”) of the proposal to serve the compliance notice and the advance notice shall—
    - (a) specify the act or omission constituting the contravention referred to in *subsection (1)* to which the advance notice relates, and
    - (b) inform the person that he or she may make representations to the Medical Council in accordance with *subsection (3)*.
  - (3) A person who is served with an advance notice may, within 21 days of the receipt of the notice, make representations to the Medical Council about the proposed compliance notice.
  - (4) Where an advance notice has been given under *subsection (2)*, the Medical Council shall within 21 days of receipt of representations (if any) consider any representations made to it and shall not issue a final decision until—
    - (a) it has considered the representations, if any, made by the applicant institution in accordance with the advance notice, or
    - (b) the period referred to in *subsection (3)* has elapsed and no representations are made by the applicant institution concerned.
  - (5) The Medical Council shall have regard to any representations made to it under *subsection (3)* in assessing whether to proceed with the service of the compliance notice.
  - (6) A compliance notice shall—
    - (a) specify the act or omission constituting contravention referred to in *subsection (1)* to which the notice relates,
    - (b) require the person on whom it is served not to commit or to cease committing, as the case may be, the act or omission concerned,
    - (c) if appropriate, specify what steps the Medical Council requires to be taken by the person on whom it is served,
    - (d) require the person on whom it is served, within the period specified in the notice to inform the Medical Council and any other persons so specified of the steps taken in order to comply with the notice, and
    - (e) require the person on whom it is served to supply, within the period specified in the notice, such additional information as may be specified in the notice.

- (7) A compliance notice shall, unless an appeal is brought under *section 83*, come into operation on the expiry of 21 days from the date of service of the notice.
- (8) Where a person on whom a compliance notice has been served fails to comply with the notice at any time within a period of 21 days from the date on which the notice comes into operation, he or she shall be guilty of an offence and shall be liable on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both.

### **Appeal of compliance notice**

- 83.** (1) A person on whom a compliance notice has been served may within 21 days of service of the compliance notice appeal to the District Court in respect of the notice or any requirement therein.
- (2) Where an appeal is brought under this section, the District Court may—
    - (a) confirm the notice in whole or in part, with or without amendment of that notice, or
    - (b) allow the appeal.
  - (3) Where the District Court allows the appeal, the compliance notice shall cease to have effect.
  - (4) Where the District Court confirms a compliance notice, the notice as so confirmed, shall unless an appeal is brought under *subsection (5)* come into operation on the expiry of 21 days of the date of confirmation or such later date as the court may determine.
  - (5) A person may within 21 days of the confirmation appeal a confirmation of a compliance notice by the District Court to the Circuit Court.
  - (6) Where the Circuit Court allows the appeal, the compliance notice shall cease to have effect.
  - (7) Where the Circuit Court confirms the compliance notice (in whole or in part, with or without amendment), the notice as so confirmed shall come into operation on such date as the Circuit Court shall determine.
  - (8) Any of the parties concerned may appeal a determination of the Circuit Court to the High Court on a point of law.
  - (9) The jurisdiction conferred on the District Court or the Circuit Court, as the case may be, under this section shall be exercised by a judge of that court for the time being assigned to the district court district or circuit, as the case may be, in which the person on whom the compliance notice is served ordinarily resides or carries on any profession, business or occupation.

## PART 5

## PUBLIC DISPLAY

**Definitions (Part 5)****84.** In this Part—

“applicant” has the meaning assigned to it by *section 89*;

“body” includes a body part or tissue sample;

“Part 5 consent” has the meaning assigned to it by *section 87*;

“Part 5 licence holder” has the meaning assigned to it by *section 86*;

“public display” means, in relation to a body of a deceased person, an exhibition, show or display in which the body, body part or the tissue of a deceased person is used for the purpose of being exposed to view (whether or not free of charge) by members of the public;

“public display activities” has the meaning assigned to it by *section 85*;

“tissue” does not include a human foetus or gamete.

**Public display activities**

**85.** (1) A person shall not use the body of a child, human foetus, embryo or gamete for purposes of public display.

(2) Public display activities means, in relation to a body of a deceased person, any of the following:

(a) the use of the body for the purposes of public display;

(b) the removal, retention, storage and transport of the body for the purposes of public display;

(c) the disposal of the body once its use for the purposes of public display is concluded;

(d) such other activities as relate to use of the body that is or is proposed to be placed on public display as may be specified by the Medical Council in accordance with *subsection (4)*,

but does not include the activities specified in *subsection (3)*.

(3) The activities referred to in *subsection (2)* are as follows, namely:

(a) display of a body of a deceased person as part of a funeral or any similar ceremony where such funeral or like ceremony is held for the purposes of paying respects to the deceased person;

(b) display of a body at a place of public religious worship and where such display is necessary to the act of religious worship;

- (c) display of a body in print, photographic or digital form, including on the internet;
  - (d) display of a body for the purposes of recording, by film or otherwise.
- (4) Subject to *subsection (6)*, the Medical Council, having had regard to the matters referred to in *subsection (5)*, may specify as public display activities such other activities relating to the exhibition, show or display of a body of a deceased person as it considers appropriate.
- (5) When specifying an activity under *subsection (4)* as a public display activity, the Medical Council shall have regard to the following:
- (a) the purpose of the proposed exhibition, show or display;
  - (b) the nature of the proposed exhibition, show or display;
  - (c) the degree to which the proposed exhibition, show or display is to be accessible to members of the public.
- (6) Before specifying an activity under *subsection (4)* as a public display activity, the Medical Council may consult such other persons as the Medical Council considers appropriate for the purposes of *subsection (4)*.

#### **Licence required for public display activities**

86. (1) Subject to *subsection (2)*, a person shall not undertake public display activities unless the person undertaking the activity holds a licence issued in accordance with this Part in respect of such public display activity (in this Part referred to as a “*Part 5 licence*”).
- (2) *Subsection (1)* shall not apply—
- (a) in respect of the public display of a body of a deceased person who died before the commencement of this section, and in respect of whom at least 100 years has lapsed since the death of the person, or
  - (b) in respect of an anatomical specimen which immediately before the commencement of this section is held by a licensed institution (within the meaning of *Part 4*), hospital, university, museum, gallery or other like place, howsoever described.
- (3) A person who holds a *Part 5 licence* (in this Part referred to as a “*Part 5 licence holder*”) shall ensure that the bodies of deceased persons used for the purposes of public display activities are treated at all times with dignity and respect.
- (4) A *Part 5 licence holder* shall not use a body for public display activities where—
- (a) any procedure related to anatomical examination is being carried out on the body,
  - (b) any similar procedure to anatomical examination is being carried out on the body, or
  - (c) if the identity of a body could be, or could reasonably be expected to be, ascertained by a member of the public when viewing such body.



- (5) A person who contravenes—
- (a) *subsection (1)*, or
  - (b) *subsection (4)*,
- shall be guilty of an offence.
- (6) In this section, “similar procedure” includes dissection, removal or implantation.

**Consent to donation of body, etc. for public display activities**

- 87.** (1) Subject to *subsection (6)*, a person shall not use a body for purposes of public display activities unless the person—
- (a) is a *Part 5* licence holder, and
  - (b) is in receipt of a consent in respect of that body, given in accordance with this section.
- (2) A person who has attained the age of 18 years may give his or her consent (in this Part referred to as a “*Part 5* consent”) to the donation of his or her body to a *Part 5* licence holder for the purposes of public display activities.
- (3) Where a person is considering whether to provide a *Part 5* consent, the *Part 5* licence holder shall provide or cause to be provided to the person information regarding the following matters:
- (a) the nature of the public display activities for which a donated body may be used;
  - (b) the length of time in respect of which a donated body may be retained;
  - (c) information relating to the loan or transfer of a donated body of a deceased person;
  - (d) information relating to the cremation, burial or disposal of a donated body;
  - (e) without prejudice to *paragraphs (a) to (d)*, any other information for the time being specified by the Medical Council as being necessary information to be given to a person who is considering providing his or her consent under this section.
- (4) A *Part 5* consent shall be given in the form for the time being standing specified by the Medical Council for the purposes of this Part and without prejudice to the generality of the foregoing shall—
- (a) be signed by the person in the presence of at least one witness who shall attest the signature,
  - (b) include a confirmation by the person concerned that he or she has been furnished with, and understands, the information referred to in *paragraphs (a) to (e)* of *subsection (3)*,

- (c) include a confirmation that the person understands that his or her body may be loaned, or transferred within the State or Northern Ireland for purposes of public display activities, and
  - (d) specify the duration of time, being a period of time that the person consents to his or her body being used for public display activities.
- (5) A *Part 5* consent given by a person may be revoked or amended by the person at any time before his or her death in like manner and subject to like conditions (if any) by notifying in writing the *Part 5* licence holder in the form for the time being standing specified by the Medical Council for that purpose in respect of which the *Part 5* consent relates.
- (6) For the purposes of *subsection (1)* and without prejudice to the generality of *section 86(2)*, a *Part 5* consent shall not be required for the removal, storage or use of a deceased person's body or material from his or her body for public display activities if—
- (a) the person concerned died before the commencement of *section 86*, and a period of 100 years has lapsed since the death of that person, or
  - (b) in respect of an anatomical specimen which, immediately before the commencement of *section 86*, is held by a licensed institution (within the meaning of *Part 4*), hospital, university, museum, gallery or other like place, howsoever described.
- (7) A person shall not be entitled to financial or other like reward for the giving of his or her consent under this section other than in respect of financial assistance with the provision of a coffin and transportation of the donated body to the place of burial or cremation, the subject of the consent and, any financial or other like reward given in respect of a consent shall render the consent null and void.
- (8) Subject to any provisions to the contrary provided for in a *Part 5* consent, a *Part 5* licence holder or a person nominated for the purposes of this subsection and specified in the *Part 5* licence as being such a person, may bury (whether in a place owned by or under the control of, the *Part 5* licence holder concerned or in a place designated by the holder concerned for that purpose) the remains, or the cremated remains as the case may be, of a body the subject of a *Part 5* consent.
- (9) A *Part 5* consent given by a person under this section operates as a consent given for the purposes and only the purposes of public display activities.
- (10) A copy of the *Part 5* consent shall be kept at the premises of the *Part 5* licence holder which received the donated body for such period as shall be specified in a code of practice under *section 100* which period shall not be less than 5 years.
- (11) A person who contravenes *subsection (1)* shall be guilty of an offence.

**Medical certificate of cause of death must be signed before public display activities can take place**

- 88.** (1) Where a person has given a *Part 5* consent, to the use of his or her body after death for public display activities, on his or her death, the deceased person's body may be brought to the premises of the *Part 5* licence holder concerned before the deceased person's death has been duly registered in the register of deaths by an tArd-Chláraitheoir.
- (2) No public display activities can take place until a medical certificate of the cause of death has been signed and furnished to the *Part 5* licence holder in respect of the body.
- (3) A copy of medical certificate of the cause of death shall be kept at the premises of the *Part 5* licence holder which received the body for such period as shall be specified in a code of practice under *section 100* which period shall not be less than 5 years.

**Application for *Part 5* licence to undertake public display activities**

- 89.** (1) A person shall not undertake public display activities unless he or she is in receipt of a licence granted under this Part to undertake public display activities (in this Part referred to as a "*Part 5* licence holder").
- (2) Where a person (in this Part referred to as the "applicant") proposes to undertake public display activities, he or she may make an application to the Medical Council for a *Part 5* licence.
- (3) An application for a *Part 5* licence shall—
- (a) be made in writing to the Medical Council in the form for the time being specified by the Medical Council,
  - (b) include particulars of the proposed public display activity, including particulars in respect of the premises, duration and content of the public display activity, the subject of the application concerned,
  - (c) specify details such as to demonstrate that sufficient procedures are in place for the purposes of this Part, including in respect of the disposal, repatriation or return of the body, which details shall include where required, the name and address of persons overseeing the implementation of those procedures,
  - (d) include copies of the *Part 5* consents relating to each of the anatomical specimens proposed to be used for the purposes of the public display activity,
  - (e) without prejudice to the generality of *paragraph (d)* in the case of an application for a licence for public display activities (whether such public display activity is on a temporary basis or otherwise) which proposes to use anatomical specimens from a state other than the State—
    - (i) include documentary evidence of the country of origin of each anatomical specimen,

- (ii) furnish a copy of consents or written evidence to the satisfaction of the Medical Council in respect of each of the anatomical specimens,
  - (iii) include evidence, in respect of each of the anatomical specimens, of compliance with the legal requirements in respect of each of the anatomical specimens of the country of origin of each of the anatomical specimens concerned, and
  - (iv) provide such additional particulars as may be determined in guidance drawn up by the Medical Council with respect of the importation of anatomical specimens for the purposes of public display activities,
- and
- (f) be accompanied by the fee as determined by the Medical Council under *subsection (11)*.
- (4) Subject to *subsection (5)*, where the Medical Council receives an application under *subsection (1)*, the Council may—
- (a) grant the licence,
  - (b) grant the licence subject to such conditions as it may impose, or
  - (c) refuse the licence.
- (5) Where the Medical Council receives an application under *subsection (2)* which seeks as part of that application to import anatomical specimens from a state other than the State, the Medical Council shall not issue a licence for that purpose unless it is satisfied that the requirements relating to the donation and use of anatomical specimens in place in that state are of a like standard to the requirements of this Part.
- (6) Where the Medical Council grants a licence under this section, the Council shall notify the applicant of the grant of the licence and such notification shall specify—
- (a) the name of the person who is licensed to carry out the public display activities, the subject of the licence concerned,
  - (b) the premises at which the public display activities may be undertaken,
  - (c) whether the licence holder is permitted under the licence to import an anatomical specimen,
  - (d) the period of operation of the licence, and
  - (e) in the case of a licence which is subject to conditions under *section 90*, the conditions which apply to the licence concerned.
- (7) Where the Medical Council proposes to refuse to grant a licence, the Council shall notify the applicant in writing of the proposed refusal and the notification shall state—
- (a) the reasons for the proposed refusal,

- (b) that the applicant may make representations in writing within 21 days of the notification, and
- (c) that no decision shall be finalised until—
  - (i) the Medical Council has considered any representations made to it by or on behalf of the applicant, or
  - (ii) in the case of no representations being made, until the expiry of 21 days.
- (8) An applicant who receives notification of a proposed refusal under *subsection (7)* may within 21 days of receipt of such notification, make representations in writing to the Medical Council in respect of the proposal by the Medical Council to refuse the application for a licence.
- (9) Where a notification has been given under *subsection (7)*, the Medical Council shall within 21 days of receipt of representations (if any) consider any representations made to it and shall not issue a final decision until—
  - (a) it has considered the representations, if any, made by the applicant institution in accordance with the notification, or
  - (b) the period referred to in *subsection (8)* has elapsed and no representations are made by the applicant institution concerned.
- (10) Where the Medical Council, having considered such representations, if any, made to it in that behalf by or on behalf of the applicant, decides to refuse the application for a licence under this section, it shall notify the applicant in writing of that fact and the notice shall state—
  - (a) the reasons for the refusal of the licence, the subject of the application, and
  - (b) that the applicant may appeal the refusal under *section 93*.
- (11) The Medical Council may, with the consent of the Minister, charge such fee as the Council may determine, to accompany an application made under *subsection (1)* and different fees may be determined and charged for different classes of application.
- (12) A person who contravenes *subsection (1)* shall be guilty of an offence.

### **Placing of conditions upon licence**

- 90.** (1) Without prejudice to the generality of *section 89(4)(b)*, the Medical Council may vary, remove or place additional conditions on a *Part 5* licence granted under *section 89*.
- (2) Where the Medical Council proposes to vary, remove or impose additional conditions on a *Part 5* licence, the Council shall notify the *Part 5* licence holder in writing of the proposal and the notice shall specify—
  - (a) particulars of the condition which the Medical Council proposes to vary, remove or additionally place on the licence, the subject of the notice concerned,
  - (b) the reasons for the proposed variation, removal or additional imposition of conditions,

- (c) subject to *paragraph (d)*, the date on which, being a date not earlier than 21 days from the date of the notice, the variation, removal or additional imposition of the condition concerned shall apply, and
- (d) that no decision shall be finalised until—
  - (i) the Medical Council has considered any representations made to it, or
  - (ii) in the case of no representations being made, the expiry of 21 days.
- (3) A *Part 5* licence holder who receives notice of a proposal under *subsection (2)* may within 21 days of receipt of such notice, make representations in writing to the Medical Council in respect of the proposal.
- (4) Where a notice has been given under *subsection (2)*, the Medical Council shall within 21 days of receipt of representations (if any) consider any representations made to it and shall not issue a final decision until—
  - (a) it has considered the representations, if any, made by the applicant institution in accordance with the notice, or
  - (b) the period referred to in *subsection (3)* has elapsed and no representations are made by the *Part 5* licence holder concerned.
- (5) Where the Medical Council, having considered within 21 days of such representations, if any, made to it in that behalf by or on behalf of the *Part 5* licence holder, decides to vary, remove or impose additional conditions on the licence under this section, it shall notify the *Part 5* licence holder in writing of that fact and the notice shall—
  - (a) specify the particulars of the conditions varied, removed or additionally placed on the licence pursuant to the decision,
  - (b) state the reasons for the decision, and
  - (c) state that the applicant may appeal the refusal under *section 93*.

### **Suspension and revocation of *Part 5* licences**

- 91.** (1) The Medical Council may suspend or revoke a *Part 5* licence, where the Council reasonably believes any of the following:
- (a) the *Part 5* licence holder is undertaking public display activities otherwise than in accordance with this Part;
  - (b) that notwithstanding the service by the Medical Council of a compliance notice under *section 101*, on the *Part 5* licence holder for the time being in operation—
    - (i) the practices of the *Part 5* licence holder as regards storage, access to or use, treatment (including the treatment with dignity) and display of anatomical specimens is such that the public display activities, the subject of the licence, cannot or can no longer be carried on safely and in accordance with this Part by the holder of the licence, or

- (ii) the premises specified in the *Part 5* licence as being the premises at which public display activities are carried on or are to be carried on is not or is no longer suitable (whether by reason of insufficient staff, equipment or facilities or otherwise) for public display activities;
  - (c) the information furnished to the Medical Council in the application under *section 89* for a *Part 5* licence was false or incomplete in any material aspect;
  - (d) the *Part 5* licence holder has notified the Medical Council in writing that the holder of the licence is not or no longer intends to carry on public display activities to which the licence relates.
- (2) Where the Medical Council proposes to suspend or revoke a *Part 5* licence under *subsection (1)*, it shall notify the *Part 5* licence holder in writing of the proposal and such notice shall specify—
  - (a) the reasons for the proposed suspension or revocation, as the case may be,
  - (b) subject to *paragraph (c)*, the date on which, being a date not earlier than 21 days from the date of the notice, the suspension or revocation, as the case may be, shall apply,
  - (c) that the Medical Council shall consider any representations made to it in that behalf within 21 days of receipt of those representations, and
  - (d) that no decision shall be finalised until—
    - (i) the Medical Council has considered any representations made to it by or on behalf of the *Part 5* licence holder, or
    - (ii) in the case of no representations being made, the expiry of 21 days or such further period as the Medical Council for good reason allows.
- (3) A *Part 5* licence holder who receives a notification under *subsection (2)* may within 21 days of the notice make representations in writing in respect of the proposal by the Medical Council to suspend or revoke the licence.
- (4) Where a notice has been given under *subsection (3)*, the Medical Council shall within 21 days of the notice consider any representations made to it and shall not issue a final decision until—
  - (a) it has considered the representations, if any, made by the person in accordance with the notice, or
  - (b) the period referred to in *subsection (3)* has elapsed and no representations are made by the *Part 5* licence holder concerned.
- (5) Where the Medical Council, having considered the representations, if any, made to it by or on behalf of a *Part 5* licence holder decides to suspend or revoke a licence, it shall notify the *Part 5* licence holder concerned in writing of the decision and such notice shall specify—
  - (a) the reasons for the suspension or revocation, as the case may be of the *Part 5* licence, the subject of the decision and the date on which it takes effect, and

- (b) that the *Part 5* licence holder may appeal the decision under *section 93*.
- (6) Where the Medical Council suspends a *Part 5* licence under *subsection (5)*, the Medical Council may, if it considers it necessary in all the circumstances to do so, extend the period of suspension but where it proposes to do so, *subsection (2)* shall with all necessary modifications apply to the proposal to extend the suspension as it applies to the proposal to suspend a licence.
- (7) An appeal shall lie under *section 93* to the High Court from the suspension or revocation of a *Part 5* licence order but the bringing of such an appeal shall not affect the operation of the suspension or prohibition order, as the case may be, unless the High Court, on application to it in that behalf within 21 days from the date of the decision of the Medical Council, makes an order staying its operation pending the determination of the appeal.

### **Suspension of licence without notice in certain circumstances**

92. (1) Where the Medical Council considers that due to the manner in which anatomical specimens are stored, treated or displayed at the premises to which the *Part 5* licence applies that—
- (a) there is a serious and immediate risk to the life, health or welfare of the public, or
  - (b) the *Part 5* licence holder is failing to treat the anatomical specimen with dignity and respect,
- the Medical Council may without giving notice under *section 91(2)* suspend the licence for a period not exceeding 21 days and, the licence concerned shall stand suspended and shall have effect for a period not exceeding 21 days beginning on such date as shall be specified in a notice in writing served under this subsection on the *Part 5* licence holder concerned and the suspension shall cease to have effect—
- (i) subject to *subparagraphs (ii)* and *(iii)*, on the expiry of the date specified in the notice,
  - (ii) in a case which falls to be determined by the Medical Council under *section 91(2)* before the date specified in the notice, on the determination of the Medical Council under *section 91(2)*, or
  - (iii) in a case where the *Part 5* licence holder, the subject matter of the suspension makes, within the period specified in the notice, an application to the High Court under *subsection (3)*, on the date determined by the High Court.
- (2) Where the Medical Council decides to suspend a licence under *subsection (1)*, the Council shall, as soon as may be, notify the *Part 5* licence holder in writing—
- (a) of the decision and the reasons for it,
  - (b) of the period for which the suspension shall have effect, and



- (c) that the licence holder may on notice make an application in a summary manner to the High Court for consideration and determination by the court of the suspension of the licence concerned.
- (3) A *Part 5* licence holder who is aggrieved by a decision of the Medical Council under *subsection (1)* may make an application in a summary manner to the High Court for consideration and determination by the court of the decision of the Medical Council.
- (4) The High Court may, on the hearing of an application under *subsection (3)* by a person, consider any evidence adduced or argument made, whether adduced or made to the Council and may—
  - (a) either—
    - (i) confirm the decision the subject of the application, or
    - (ii) cancel that decision and replace it with such other decision as the High Court considers appropriate,and
  - (b) give the Medical Council such direction as the High Court considers appropriate and direct how the costs of the application are to be borne.

#### **Appeal from decision (other than decision under *section 92*) of Medical Council**

- 93.** (1) A person who is aggrieved by a decision under *section 89, 90* or *91* may not later than 21 days after the person received notice of the decision under *section 89, 90* or *91* as the case may be, appeal to the High Court against the decision.
- (2) The High Court may, on the hearing of an appeal under *subsection (1)* by a person, consider any evidence adduced or argument made, whether adduced or made to the Council.
  - (3) The High Court may, on the hearing of an appeal under *subsection (1)* by a person—
    - (a) either—
      - (i) confirm the decision the subject of the appeal, or
      - (ii) cancel that decision and replace it with such other decision as the High Court considers appropriate,and
    - (b) give the Medical Council such direction as the High Court considers appropriate and direct how the costs of the appeal are to be borne.

#### **Loan or transfer of anatomical specimens for purposes of public display activities**

- 94.** (1) A *Part 5* licence holder, if he or she is in receipt of a prior authorisation given to the holder by the Medical Council, may by agreement loan or transfer an anatomical specimen to another *Part 5* licence holder or a holder of a like licence in Northern Ireland for the purposes of public display activities.

- (2) In making an application to the Medical Council for an authorisation, a *Part 5* licence holder shall specify in writing—
  - (a) the anatomical specimens that are the subject of the loan or transfer, as the case may be,
  - (b) that *Part 5* consent has been given in respect of the anatomical specimens that are the subject of the loan or transfer, as the case may be,
  - (c) the purpose for which the loan or transfer as the case may be, is being made,
  - (d) in the case of a loan, the duration of the loan period, and
  - (e) the name and location of the place where the anatomical specimens will be put on display.
- (3) An anatomical specimen that is on loan under *subsection (1)* shall remain the responsibility of the *Part 5* licence holder who made the loan.
- (4) An anatomical specimen that is transferred to a *Part 5* licence holder or transferred to a like licence holder in Northern Ireland shall be the responsibility of—
  - (a) in the case of a transfer to another *Part 5* licence holder, that other *Part 5* licence holder, or
  - (b) in the case of a transfer to a like licence holder in Northern Ireland in accordance with this section, the licence holder to which the anatomical specimen is transferred.
- (5) It shall be for both the *Part 5* licence holder which loans or transfers, as the case may be, an anatomical specimen, and the like licence holder which receives an anatomical specimen on loan or transfer, as the case may be, to satisfy himself or herself and show if so requested in writing by the Medical Council that the loan or transfer was made in accordance with any *Part 5* consent in respect of the anatomical specimen concerned.
- (6) All records (which shall include a copy of the records referred to in *section 95* and *96* relating to anatomical specimens) shall be transferred from the *Part 5* licence holder to the other *Part 5* licence holder or like licence holder in Northern Ireland, as the case may be, receiving the anatomical specimen the subject of the transfer as the case may be.
- (7) A *Part 5* licence holder who loans or transfers an anatomical specimen under this section shall retain copies of the records transferred under *subsection (6)* for such period as shall be specified in a code of practice under *section 100* which period shall not be less than 5 years.
- (8) A *Part 5* licence holder or like licence holder in Northern Ireland, as the case may be, receiving an anatomical specimen shall be responsible—
  - (a) in the case of a loan, for the return of that anatomical specimen to the *Part 5* licence holder who made the loan, or

- (b) in the case of a transfer, for the disposal of that anatomical specimen in accordance with the consent provided.

#### **Importation of anatomical specimens for purposes of public display activities**

95. (1) A *Part 5* licence holder may, if he or she is in receipt of prior authorisation issued as part of the licence issued to the holder in that behalf by the Medical Council, import an anatomical specimen for the purposes of public display activities.
- (2) In making an application to the Medical Council for an authorisation, the licence holder shall specify in writing—
- (a) the anatomical specimens that are the subject of the proposed importation,
  - (b) that consent has been given in respect of the anatomical specimens that are the subject of the proposed importation,
  - (c) the purpose for which the importation is being made,
  - (d) in the case of a loan, the duration of the loan period, and
  - (e) the location where the anatomical specimens will be held.
- (3) An imported anatomical specimen shall be obtained, transported, used and disposed of by a *Part 5* licence holder in accordance with any consent given by the donor in respect of the anatomical specimen concerned.
- (4) It shall be for the *Part 5* licence holder to satisfy himself or herself and show, if so requested in writing by the Medical Council, that the anatomical specimen has been obtained, transported, used and disposed of by the licence holder concerned in accordance with any consent given by the donor of the anatomical specimen concerned.
- (5) Where an anatomical specimen is imported into the State by a *Part 5* licence holder for the purposes of public display activities, it shall be for the *Part 5* licence holder to show, if so requested in writing by the Medical Council, that the licence holder complied with the legal requirements in the country from which the anatomical specimen has been imported.
- (6) Without prejudice to the generality of *subsection (5)*, evidence of compliance referred to in that subsection may comprise of evidence to show that the anatomical specimen has been imported in accordance with rules relating to public display activities where such rules are, in the view of the Medical Council, equivalent to the provisions of this Part.

#### **Records to be kept in relation to anatomical specimens**

96. (1) A *Part 5* licence holder shall keep a register containing the following documents (in this Part referred to as a “*Part 5 Register*”):
- (a) in the case of anatomical specimens which are imported for the purposes of public display activities—

- (i) documentary evidence of the country of origin of each anatomical specimen,
  - (ii) documentary evidence of consent in respect of each of the anatomical specimens,
  - (iii) documentary evidence of compliance with legal requirements in operation in respect of each of the anatomical specimens of the country of origin of each of the anatomical specimens concerned, and
  - (iv) such additional particulars as may be determined in guidance drawn up by the Medical Council with respect of the importation of anatomical specimens for the purposes of public display activities;
- (b) in any other case—
- (i) a copy of the medical certificate of the cause of death,
  - (ii) a copy of the *Part 5* consent of each of the anatomical specimens used or proposed to be used for the purposes of public display activities.
- (2) The *Part 5* Register shall be—
- (a) maintained in a secure and permanent form, and
  - (b) made available for inspection by the Medical Council.
- (3) A person who contravenes *subsection (1)* shall be guilty of an offence.

**Medical Council to monitor compliance with provisions of *Part 5***

97. (1) The Medical Council shall monitor compliance with this Part.

- (2) For the purposes of *subsection (1)*, the Medical Council—
- (a) shall undertake or shall cause to be undertaken, inspections of, and provide or cause to be provided, reports on, premises identified in applications made by applicants for a *Part 5* licence,
  - (b) without prejudice to the generality of *paragraph (a)*, shall conduct inspections not less than once every 3 years of all licensed institutions at which public display activities are undertaken,
  - (c) without prejudice to *sections 89* and *101*, may request an applicant or a *Part 5* licence holder to provide to the Medical Council as soon as it is practicable after receipt of such request, such information as the Medical Council may reasonably require for the purposes of this section and is so specified in its request,
  - (d) shall do such other things as are reasonably necessary or expedient for the purposes of monitoring compliance with this Part,
  - (e) may appoint one or more authorised officers to undertake any of the functions referred to in *paragraphs (a) to (d)* of this subsection.

**Authorised officers for purposes of Part 5**

98. (1) The Medical Council may appoint one or more persons as the Council sees fit to be authorised officers for the purposes of this Part.
- (2) Each authorised officer shall be furnished with a warrant of his or her appointment and, when exercising a power conferred by this Part shall, if requested by any person affected thereby, produce such warrant of appointment to that person for inspection.
- (3) An appointment under this section shall cease—
- (a) if the Medical Council revokes the appointment,
  - (b) if the appointment is for a fixed period, on the expiry of that period, or
  - (c) in the case of a person who is a member of the staff of the Medical Council, if the person ceases to be a member of the staff.

**Powers of authorised officers - Part 5**

99. (1) For the purposes of this Part, an authorised officer may exercise any of the following powers:
- (a) enter (if necessary by use of reasonable force) and inspect, at any reasonable time, any premises (other than a dwelling)—
    - (i) specified in a *Part 5* licence,
    - (ii) not specified in a *Part 5* licence but at which he or she has reasonable grounds for believing that public display activities are being undertaken, or
    - (iii) at which he or she has reasonable grounds for believing that documents or records relating to public display activities are kept;
  - (b) require any person on the premises referred to in *paragraph (a)* to produce any documents or records relating to public display activities;
  - (c) secure for inspection—
    - (i) any documents or records relating to public display activities, or
    - (ii) any premises (or part thereof) in which documents or records relating to public display activities are kept;
  - (d) take samples, carry out, or have carried out, such tests, examinations, analyses, inspections or checks of any or all of the following as he or she considers reasonably necessary for the purposes of this Part:
    - (i) the premises;
    - (ii) anything at the premises;
    - (iii) without prejudice to the generality of *subparagraph (ii)*, any equipment, machinery or plant at the premises;

- (e) require any person at the premises or the owner or person in charge of the premises and any person employed there to give 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 the person's power or procurement, as the authorised officer may reasonably require for the purposes of this Part.
- (2) An authorised officer shall not enter a dwelling, other than—
  - (a) with the consent of the occupier, or
  - (b) pursuant to a warrant under *subsection (3)*.
- (3) Upon the sworn information of an authorised officer, a judge of the District Court may, for the purposes of enabling an authorised officer to carry out an inspection under *subsection (1)*, issue a warrant authorising a named authorised officer, accompanied by such other authorised officers or members of the Garda Síochána as may be necessary, at any time or times, before the expiration of one month from the date of issue of the warrant, to enter (if necessary by use of reasonable force) the dwelling and perform the functions of an authorised officer under *subsection (1)*.
- (4) A person shall be guilty of an offence if he or she—
  - (a) obstructs or interferes with an authorised officer or a member of the Garda Síochána in the course of exercising a power conferred on him or her by this Part or a warrant under *subsection (3)*, or impedes the exercise by the person or member, as the case may be, of such power, or
  - (b) fails or refuses to comply with a request or requirement of, or to answer a question asked by, an authorised officer or member pursuant to this section, or in purported compliance with such request or requirement or in answer to such question, give information to an authorised officer or member that he or she knows to be false or misleading in a material particular.
- (5) Where an authorised officer believes, upon reasonable grounds, that a person has committed an offence under this Part, the authorised officer may require that person to provide him or her with his or her name and the address at which they ordinarily reside and the person shall comply with that requirement.
- (6) A person who is guilty of an offence under *paragraph (a)* or *(b)* of *subsection (4)* shall be liable on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both.

**Codes of practice (public display)**

**100.** (1) Subject to *subsection (2)*, the Medical Council—

- (a) may, and, at the request of the Minister, shall prepare and publish a code of practice for the purpose of setting standards relating to the undertaking of public display activities which standards shall include the time periods for which records are required to be retained, or

- (b) may, if it thinks appropriate to do so, approve any other code of practice relating to the undertaking of public display activities.
- (2) Before publishing or approving of codes of practice under this section, the Medical Council—
  - (a) shall publish in such manner as the Council considers appropriate a draft of the code of practice and shall allow persons 30 days from the date of publication of the draft code of practice within which to make representations in writing to the Medical Council in relation to the draft code of practice or such further period, not exceeding 30 days, as the Medical Council in its absolute discretion thinks fit, and
  - (b) following consultation and, where relevant, having considered the representations (if any) made, shall submit the draft code of practice to the Minister for his or her consent to its publication or approval of under this section, with or without modifications.
- (3) The Minister may—
  - (a) consent to the publication or approval of, as the case may be, a code of practice under this section with or without modification, or
  - (b) refuse to consent to publication or approval of such a code of practice.
- (4) Where the Medical Council publishes or approves codes of practice under this section, the Medical Council shall cause a notice to that effect to be published in *Iris Oifigiúil*—
  - (a) identifying or specifying the code of practice, and
  - (b) specifying the date from which the code of practice shall have effect.
- (5) The Medical Council may, with the consent of the Minister but subject to *subsection (6)*—
  - (a) amend or revoke codes of practice published under this section, or
  - (b) withdraw its approval of any code of practice approved of under this section.
- (6) *Subsection (2)* shall, with all necessary modifications, apply to codes of practice that the Medical Council proposes to amend or revoke, or withdraw its approval of, under *subsection (5)* as *subsection (2)* applies to a code of practice that the Medical Council proposes to publish or approve of under this section.
- (7) Where the Medical Council amends or revokes, or withdraws its approval of, a code of practice published or approved of under this section, the Medical Council shall cause a notice to that effect to be published in *Iris Oifigiúil*—
  - (a) identifying or specifying the code of practice to which the amendment, revocation, or withdrawal, as the case may be, relates and, if applicable, particulars of the amendment, and

- (b) specifying the date from which the amendment, revocation, or withdrawal, as the case may be, shall have effect.
- (8) The Medical Council shall maintain on its website a copy of each of the codes of practice published or approved of under this section, as the codes of practice are in force from time to time, on and from the date on which the codes of practice have effect.
- (9) A document bearing the seal of the Medical Council and purporting to be a code of practice published or approved of under this section or, where such codes of practice have been amended under this section, the codes of practice as so amended shall be admissible in evidence in any proceedings under this Act.
- (10) In this section, “code of practice” includes part of a code of practice.

**Compliance notices (public display)**

**101.** (1) Where the Medical Council is of the opinion that a *Part 5* licence holder has contravened or is contravening—

- (a) the provisions of this Part,
- (b) any conditions which have been placed on any licence issued to a *Part 5* licence holder under this Part, or
- (c) any codes of practice for the time being in force in respect of public display activities,

the Medical Council may serve a compliance notice on the *Part 5* licence holder.

- (2) Before serving a compliance notice on a person under *subsection (1)*, the Medical Council shall give the person notice (in this section referred to as “advance notice”) of the proposal to serve the compliance notice and the advance notice shall—
  - (a) specify the act or omission constituting the contravention referred to in *subsection (1)* to which the notice relates, and
  - (b) inform the person that he or she may make representations to the Medical Council in accordance with *subsection (3)*.
- (3) A person who is given an advance notice may, within 21 days of the receipt of the notice, make representations to the Medical Council about the proposed compliance notice.
- (4) Where a notice has been given under *subsection (2)*, the Medical Council shall within 21 days of receipt of representations (if any) consider any representations made to it and shall not issue a final decision until—
  - (a) it has considered the representations, if any, made by the *Part 5* licence holder in accordance with the notice, or
  - (b) the period referred to in *subsection (3)* has elapsed and no representations are made by the *Part 5* licence holder concerned.



- (5) The Medical Council shall have regard to any representations made to it under *subsection (3)* in assessing whether to proceed with the service of the compliance notice.
- (6) A compliance notice shall—
  - (a) specify the act or omission constituting contravention referred to in *subsection (1)* to which the notice relates,
  - (b) require the person on whom it is served not to commit or to cease committing, as the case may be, the act or omission concerned,
  - (c) if appropriate, specify what steps the Medical Council requires to be taken by the person on whom it is served,
  - (d) require the person on whom it is served, within the period specified in the notice to inform the Medical Council and any other persons so specified of the steps taken in order to comply with the notice, and
  - (e) require the person on whom it is served to supply, within the period specified in the notice, such additional information as may be specified in the notice.
- (7) A compliance notice shall, unless an appeal is brought under *section 102*, come into operation on the expiry of 21 days from the service of the notice.
- (8) Where a person on whom a compliance notice has been served fails to comply with the notice at any time within a period 21 days from the date on which the notice comes into operation, he or she shall be guilty of an offence and shall be liable on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both.

### **Appeal of compliance notice**

- 102.** (1) A person on whom a compliance notice has been served may within 21 days of service of the notice appeal to the District Court in respect of the notice or any requirement therein.
- (2) Where an appeal is brought under this section, the District Court may—
    - (a) confirm the notice in whole or in part, with or without amendment of that notice,  
or
    - (b) allow the appeal.
  - (3) Where the District Court allows the appeal, the compliance notice shall cease to have effect.
  - (4) Where the District Court confirms a compliance notice, the notice as so confirmed, shall, unless an appeal is brought under *subsection (5)*, come into operation on the expiry of 21 days of the date of confirmation or such later date as the court may determine.

- (5) A person may within 21 days appeal a confirmation of a compliance notice by the District Court to the Circuit Court.
- (6) Where the Circuit Court allows the appeal, the compliance notice shall cease to have effect.
- (7) Where the Circuit Court confirms the compliance notice (in whole or in part, with or without amendment), the notice as so confirmed shall come into operation on such date as the Circuit Court shall determine.
- (8) Any of the parties concerned may appeal a determination of the Circuit Court to the High Court on a point of law.
- (9) The jurisdiction conferred on the District Court or the Circuit Court, as the case may be, under this section shall be exercised by a judge of that court for the time being assigned to the district court district or circuit, as the case may be, in which the person on whom the compliance notice is served ordinarily resides or carries on any profession, business or occupation.

## PART 6

### MISCELLANEOUS

#### **Amendment of Health Act 2004**

**103.** The Health Act 2004 is amended, in section 55G, by the substitution of the following paragraph for paragraph (a):

- “(a) an authorised person appointed by the Health Information and Quality Authority in accordance with section 70 of the Health Act 2007 to—
- (i) monitor compliance with standards in accordance with section 8(1)(c) of the Health Act 2007,
  - (ii) undertake an investigation under section 9 of the Health Act 2007,
  - (iii) monitor compliance, under section 8(1)(o) of the Health Act 2007, with *Part 3* of the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024*, or
  - (iv) monitor compliance, under section 8(1)(p) of the Health Act 2007, with the relevant sections (within the meaning of the Health Act 2007) of the Coroners Act 1962 and regulations made by the Minister for Justice under section 33I of that Act.”

**Amendment of Act of 2007**

**104.** The Act of 2007 is amended in section 7(2), by the insertion of the following paragraphs after paragraph (k):

- “(ka) issue licences under *Parts 4 and 5* of the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024* (“the *Act of 2024*”),
- (kb) monitor compliance with *Parts 4 and 5* of the *Act of 2024*,
- (kc) at the request of the Minister and as soon as is practicable after it receives the request, provide the Minister with such information concerning its functions under *Parts 4 and 5* of the *Act of 2024* as the Minister specifies in the request,
- (kd) issue codes of practice for the purposes of *Part 4* of the *Act of 2024*,
- (ke) issue codes of practice for the purposes of *Part 5* of the *Act of 2024*,
- (kf) perform any other function vested in the Council pursuant to the said *Parts 4 and 5* of the *Act of 2024*.”.

**Amendment of Act of 2015**

**105.** The Act of 2015 is amended, in section 4(3), by the substitution of the following paragraph for paragraph (a):

- “(a) any decision regarding the donation of an organ from a living donor shall, where the donor is a person who lacks capacity, be determined in accordance with the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024*, and”.

**Repeals**

**106.** (1) Section 106 of the Act of 2007 is repealed.

(2) The Anatomy Act 1832 is repealed.

**Offences and penalties**

**107.** (1) A person guilty of an offence under—

- (a) *paragraph (b) or (c) of section 10(6)*,
- (b) *section 11(3)*,
- (c) *section 16(6)(a)*,
- (d) *section 42(3)*,

- (e) *section 45(4)(a)*,
- (f) *section 63(10)*,
- (g) *paragraph (a) or (b) of section 86(5)*,
- (h) *section 87(11)*,
- (i) *section 89(12)*,

shall be liable—

- (i) on summary conviction, to a class A fine or to imprisonment for a term not exceeding 6 months, or both, and
- (ii) on conviction on indictment, to a fine not exceeding €120,000 or to imprisonment for a term not exceeding 3 years or both.

(2) A person guilty of an offence under—

- (a) *section 10(6)(a)*,
- (b) *section 16(6)(b)*,
- (c) *section 33(8)*,
- (d) *section 45(4)(b)*,
- (e) *section 96(3)*,

shall be liable on summary conviction—

- (i) in the case of a first offence, to a class C fine or to imprisonment for a term not exceeding 6 months, or both, and
- (ii) in the case of a second or subsequent offence, to a class A fine or to imprisonment for a term not exceeding 12 months, or both.

(3) A person guilty of an offence under—

- (a) *section 12(9)*, or
- (b) *section 65(4)*,

shall be liable—

- (i) on summary conviction to a class A fine and to imprisonment for a period not exceeding 12 months or both, and
- (ii) on conviction on indictment, to a fine not exceeding €120,000 and to imprisonment for a period not exceeding 3 years or both.

(4) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under this Act may be instituted at any time within two years from the date on which the offence was alleged to have been committed.

(5) Where an offence under this Act is committed by a body corporate and is proved to have been so committed with the consent or connivance of, or to be attributable to any

wilful neglect on the part of any person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

- (6) Where the affairs of a body corporate are managed by its members, *subsection (5)* applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

### Defences

**108.** In proceedings for an offence under this Act, it shall be a defence for a person against whom such proceedings are brought to show all or any of the following:

- (a) that he or she took reasonable steps to ensure compliance with such provisions of this Act as are alleged to have been contravened;
- (b) that at the time of the activity, the person reasonably believed that the activity was carried out in accordance with the requirements of this Act.

### Sharing of information in certain circumstances

**109.** (1) Where, in the opinion of a relevant body, having had regard to the functions of the relevant body, it is necessary for the purposes of the safety of patients or in respect of *Part 3* where it is in the public interest that such information be shared with one or more other relevant bodies for the performance by any such relevant body of its functions under this Act, the relevant body may share information provided to it, or as the case may be, to him or her under, and in accordance with, this Act with any such other relevant body.

- (2) A relevant body shall use any information provided to it under this section solely for the purpose of the performance by it of its functions under and in accordance with this Part.

- (3) In this section—

“Act of 1962” means the Coroners Act 1962;

“relevant body” means any or all of the following:

- (a) the coroner (within the meaning of the Act of 1962) for the coroner’s district (within the meaning of the Act of 1962) in which a notifiable incident has occurred;
- (b) Medical Council;
- (c) the Health Products Regulatory Authority;
- (d) the Health and Safety Authority;

- (e) a body established by or under any enactment (other than the Companies Act 2014) whose functions include the carrying on of post-mortem activities.

### Data protection

**110.** (1) Subject to this section and such regulations (if any) as may be made under *subsection (8)*, personal data may be processed by a person in accordance with the Data Protection Regulation and the Act of 2018 for the purposes for the performance of functions under *Parts 2, 3, 4* and *5*.

- (2) For the purposes of *Part 2*, the Executive is designated as a data controller in relation to personal data processed pursuant to *subsection (1)*.
- (3) For the purposes of *Part 3*, the Executive is designated as a data controller in relation to personal data processed pursuant to *subsection (1)*.
- (4) For the purposes of *Part 4*, a licensed institution is designated as a data controller in relation to personal data processed pursuant to *subsection (1)*.
- (5) For the purposes of *Part 5*, a *Part 5* licence holder is designated as a data controller in relation to personal data processed pursuant to *subsection (1)*.
- (6) Subject to *subsection (7)*, personal data processed for the purposes referred to in *subsection (1)* shall not be retained for any period beyond which it is required and shall be permanently deleted after it is no longer required.
- (7) Notwithstanding *subsection (6)*, where personal data processed in accordance with this section is required for the purposes of the prevention, investigation, detection or prosecution of a criminal offence, the data—
- (a) may be processed for as long as it is required for such prevention, investigation, detection or prosecution, and
- (b) shall be permanently deleted after it is no longer required for such prevention, investigation, detection or prosecution.
- (8) The Minister may for the purposes of this Act, prescribe by regulations—
- (a) the personal data that may be processed,
- (b) the circumstances in which the personal data may be processed, including specifying the persons to whom the data may be disclosed, and
- (c) such other conditions (if any) as the Minister considers appropriate to impose on such processing.

(9) In this section—

“Act of 2018” means the Data Protection Act 2018;

“Data Protection Regulation” means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016<sup>1</sup> on the protection of natural persons

<sup>1</sup> OJ No. L 119, 4.5.2016, p.1.

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with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);

“licensed institution” has the same meaning as it has in *section 61*;

“*Part 5* licence holder” has the same meaning as it has in *section 84*;

“personal data” has the meaning it has in the General Data Protection Regulation;

“processing”, in relation to personal data, has the meaning it has in the General Data Protection Regulation.