GENERAL SCHEME OF THE HUMAN TISSUE (TRANSPLANTATION, POST-MORTEM, ANATOMICAL EXAMINATION, AND PUBLIC DISPLAY) BILL 2018

A Bill to

1) Regulate the removal, retention, storage, use and disposal of human tissue from deceased persons;
2) Provide general conditions for the removal, donation and use of organs and tissue from deceased and living persons for the purposes of transplantation; and
3) Provide for an opt-out system of consent for organ donation and for an associated register.

PART 1 – PRELIMINARY AND GENERAL MATTERS

PART 2 - TRANSPLANTATION

PART 3 – PATHOLOGY PRACTICE

PART 4 ANATOMICAL EXAMINATION

PART 5 – PUBLIC DISPLAY

PART 6 – OFFENCES AND PENALTIES

PART 1 – Preliminary and General Matters

Head 1 Short title and commencement

(1) This Act may be cited as the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination, and Public Display) Act 2018.

(2) The Act may come into operation on such day or days as the Minister may decide by order, and different days may be appointed for the commencement of different purposes or different provisions.

Explanatory Note

This Head is a standard provision for dealing with the short title and commencement provisions. The commencement provision allows for the provisions of the Act to be brought into operation on a phased basis.

Head 2 Interpretation

(1) In this Act, unless otherwise stated, the following definitions will apply:

"adult" means a person who is 18 years of age or older;

"authorised officer" means a person appointed under Heads 24, 32, 44, or 57;

"body" means human body;

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

"child" means a person who is below the age of 18;

"cohabitant" has the meaning given to it by the Civil Partnerships and Certain Rights and Obligations of Cohabitants Act, 2010;

"consent" means the giving of permission or agreement for the use of tissue for a specified purpose, in which the person giving consent has received sufficient information to allow them to understand the nature, risks, and benefits of the proposed use, that is voluntarily and freely given;

"capacity" has the meaning given to it by the Assisted Decision-Making (Capacity) Act 2015;

"coroner" means a person appointed to the office of coroner under Section 8 of the Coroners Act 1962;

"designated family member" has the meaning given to it by Head 6;

"donation" means donating human organs or tissues;

"donor" means the human source, whether living or deceased, of human organs or tissues;

"fetus" includes an embryo.

"functions" means powers and duties, and references to the performance of functions includes, with respect to powers and duties, references to the exercise of powers and the carrying out of the duties;

"guardian" has the meaning given to it by the Guardianship of Infants Act 1964;

"health professional" means a registered medical practitioner within the meaning of the Medical Practitioners Act 2007, a registered dentist within the meaning of the Dentists Act 1985, a registered nurse or midwife within the meaning of the Nurses Act 1985 (as amended by the Nurses and Midwives Act 2011) or a member of a designated profession within the meaning of Section 3 of the Health and Social Care Professionals Act 2005;

"Health Service Executive" means the body established under Section 6 of the Health Act 2004;

"HPRA" means the Health Products Regulatory Authority, as established by the Irish Medicines Board Act 1995;

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

“Medical Council” means the Council established by Section 6 of the Medical Practitioners Act 1978;

“monitoring and inspection” means formal and objective oversight by means of review of information requested and submitted and held by the regulator from and about the regulated organisation or individual, and of site visits both announced and unannounced to the regulated organisation or individual, in order to assess performance against pre-determined standards adopted to assess compliance with this Act;

“Minister” means the Minister for Health;

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

"parent" has the meaning given to it by the Guardianship of Infants Act 1964;

“pathologist” means a registered medical practitioner within the meaning of the Medical Practitioner’s Act 2007 and who meets the professional standards of a body recognised by the Medical Council for the purpose of granting evidence of satisfactory completion of specialist training;

"post-mortem examination" means examination of the body of a deceased person or fetus involving its dissection and the removal of organs, tissue samples, blood (or any material derived from blood) which is carried out for the purposes outlined in Head 30. ““Post-mortem examination” does not include any activity done for the purposes of a function of the coroner or under the authority of a coroner;

“preservation” means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of tissues;

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

“site” means any premises at which an activity regulated by this Act is carried out;

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

“storage” means maintaining relevant material under appropriate controlled conditions until distribution or disposal;

“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 a recipient and shall include the complete process of removal of an organ from one person and implantation of that organ into another person, including all procedures for preparation, preservation and storage. References to “transplant” and to “transplants” means transplantation into a human body and references to “transplant” or to “transplants” should be construed accordingly;

"writing" for the purpose of consent includes the representation of a character in visible form, such as a tick box, also includes voice, video recording and speech recognition technologies.

Explanatory Note

This Head defines key words and terms used in the Act.

The definition of "adult" is intended to refer to either a living person who is 18 years old or older, or a deceased person who, at the time of their death, was 18 years old or older. The definition of "child" is to be understood similarly.

The definition of "consent" is adapted from the HSE's document "Consent: A guide for health and social care professionals." The definition makes reference to "sufficient information" being required to allow the person giving consent to understand the nature, risks, and benefits of the proposed use. Specific provisions for what constitutes sufficient information in relation to specific activities are included throughout the Act in Heads 10, 13-18, 29, 34, 41, 49 & 54.

The definitions of "donor "and "donation" are adapted from S.I. 158 of 2006 (European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006) and S.I. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012).

The definitions of "cells", "functions" "human application" and "tissue" are from S.I. 158 of 2006 (European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006).

The definitions of "organs", "preservation", "processing", "site", and "storage" are from S.I. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012).

The definition of "monitoring and inspection" is adapted from S.I. 158 of 2006 (European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006).

The definition of "transplantation" is adapted from S.I. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012).

The definition of "specimen" is adapted from the UK's Human Tissue Act 2004.

The definition of post-mortem excludes activities performed for the purposes of a function of the coroner or under the jurisdiction of the coroner. Coroner's post-mortems are legislated for by the Coroner's Act (1962). Amendments to the Coroner's Act (1962) are proposed in the Coroners (Amendment) Bill 2018.

The provisions in Human Tissue (Transplantation, Post-Mortem, Anatomical Examination, and Public Display) Bill relate to consented post-mortems which do not involve the Coroner.

Head 3 Expenses

(1) This Head provides that the expenses incurred by the Minister in the administration of the Act shall, to such extent as may be sanctioned by the Minister for Public Expenditure and Reform, be paid out of monies provided by the Oireachtas.

Explanatory Note

This is a standard provision establishing that any expenses incurred in the administration of the legislation, once enacted, shall be paid out of monies provided by the Oireachtas.

Head 4 Regulations

(1) The Minister may by regulation provide:

a. for any matter referred to in this Act as prescribed or to be prescribed; or

b. for any matter than appears to be necessary or expedient for bringing this Act into operation.

(2) Without prejudice to any provision of this Act, regulations under this Head 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 under this Act shall be laid by the Minister before each House of the Oireachtas as soon as may be after it is made and, if a resolution annulling the order or regulation is passed by either such House within the next 21 days on which that House sits after the order or regulation is laid before it, the order or regulation shall be annulled accordingly but without prejudice to the validity of anything previously done thereunder.

Explanatory Note

This is a standard provision in regard to Ministerial powers to make regulations.

Head 5 Provisions for storage, handling, transportation, and respectful disposal or return of bodies, anatomical specimens, organs and/or tissue

(1) Storage, handling, transportation, disposal and return of organs, tissue, bodies, body parts and anatomical specimens:

a. is lawful when done in connection with an activity under Part 2, 3, 4, or 5 that has been subject to appropriate consent under this Act;

b. must be performed in such a way as to respect the dignity of the deceased person;

c. must meet any quality and safety standards which may be approved, adopted or developed by the appropriate regulator;

d. must be properly recorded so as to ensure traceability of the body or body parts stored, handled, transported, dispatched or received;

e. must meet any national laws or regulations, including directives from the Health and Safety Authority.

(2) References to storage, handling, transportation disposal and return do not include:

a. activities which are incidental to funeral arrangements, burial or cremation;

b. blood and blood components intended for transfusion, which are governed by S.I. No 360 of 2005 (European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005);

c. the storage, handling and transportation of organs for transplantation and tissue intended for human application, which are governed by S.I. No 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012) and by S.I. No 158 of 2006 (European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006);

d. activities undertaken for purposes of functions of the coroner or under the authority of the coroner under the Coroner's Act 1962;

e. matters which are connected with the enforcement or administration of law, including activities conducted as part of a criminal investigation or following a criminal conviction.

(3) Responsibility for disposal of a body lies with the deceased person's executor. Responsibility for disposal or return of anatomical specimens, organs and tissues lies with the person in lawful possession of the organs and tissue.

(4) The Minister may, by Order, make regulations for the disposal of organs and tissue which come within the scope of this Act.

Explanatory Note

This Head addresses the issue of storage, handling, and transportation, of organs, tissue, bodies, body parts and anatomical specimens in connection with transplantation, post-mortem, anatomical examination, or public display. This Head also provides for the disposal and/or return of organs, tissue, bodies, body parts and anatomical specimens to families on completion of transplantation, post-mortem, anatomical examination, or public display.

Subhead 1 provides that the storage, handling, transportation, disposal and return of bodies and body parts are lawful if it is associated with transplant (Part 2), post-mortem (Part 3), anatomical examination (Part 4), or public display (Part 5) for which appropriate consent has been received. These ancillary activities must be done in such a way as to respect the dignity of the deceased, must ensure full traceability of all bodies and body parts, and must observe accepted standards of best practice and all relevant health and safety regulations.

Subhead 2 lists exclusions from the provisions of this head. Exclusions from this Head include any activity which is ancillary to funeral arrangements, burial, or cremation.

The storage, handling, transportation, disposal, and return of blood and blood products for the purposes of transfusion are also exempt and the regulatory requirements in respect of these products when intended for human application are already covered by Statutory Instrument No. 360 of 2005 (European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005).

The storage, handling and transportation of organs for transplantation are also exempt, as the regulatory requirements in respect of these products when intended for human application are governed by Statutory Instrument No. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation Regulations).

The storage, handling and transportation of tissue for transplantation are also exempt, as the regulatory requirements in respect of these products when intended for human application are governed by Statutory Instrument No. 158 of 2006 (European Communities Quality and Safety of Human Tissues and Cells Regulations).

Subhead 3 restates the current de facto legal position, which is that responsibility for disposal of a body lies with the deceased person's executor, and that responsibility for disposal or return of organs and tissues lies with the person in lawful possession of the material.

Subhead 4 allows the Minister to make regulations for the disposal of organs and tissue that come within the scope of the Act.

Head 6 Definition of designated family member

(1) The designated family member is the person who is, or immediately before the adult's death was:

a. the adult's spouse or civil partner;

b. a cohabitant;

c. the adult's child;

d. the adult's parent;

e. the adult's brother or sister;

f. the adult's grandparent;

g. the adult's grandchild;

h. the adult's uncle or aunt; or

i. a friend of longstanding of the adult.

(2) Where the adult's spouse or civil partner:

a. was permanently separated (either by agreement or under an order of a court) from the adult; or

b. has deserted, or has been deserted by, the adult and the desertion continued,

the adult's spouse or civil partner is to be disregarded for the purposes of subhead (1).

(3) Relationships in different paragraphs of subhead (1) rank in the order of appearance of those paragraphs. For the purposes of that subhead:

a. a relationship of half-blood may be treated as a relationship of whole blood; and

b. the stepchild of an adult may be treated as the child of the adult.

(4) Consent, or confirmation that there is no objection to deemed consent (see Head 10), shall be obtained from the person whose relationship to the person concerned is accorded the highest ranking in accordance with subhead (1).

(5) Where more than one person falls within a paragraph in subhead (1), each such person ranks equally for the purpose of the paragraph; and consent by virtue of the paragraph in question may be given by any one of the persons falling within the paragraph.

(6) Where family members of equal rank are unable to reach agreement in relation to consent or confirmation that there is no objection to deemed consent, the family

members concerned will be asked to reach a consensus agreement. If no such consensus can be reached then the activity in question will not proceed.

(7) For the purposes of subhead (1), a person's relationship with the adult is to be left out of account if:

a. the person, immediately before the adult's death, was less than 18 years of age;

b. the person does not wish to or is unable to make a decision on the issue of consent or confirmation that there is no objection to deemed consent;

c. it is not reasonably practicable to communicate with the person in the time available; or

d. the relationship between the person and the adult is not known.

Explanatory Note

Subhead 1 describes a hierarchy of family members who will be considered a "designated family member" for the purposes of this Act. At the top of the list is the deceased's spouse or partner. The rest of the list follows the natural decision-making hierarchy in families. Where an individual does not have a partner or close relatives, a friend of long-standing can be considered a designated family member. The list of family members is adapted from the Civil Liabilities Act 1961. A similar hierarchy appears in Section 27(4) of UK's Human Tissue Act 2004 and Section 50 of the Human Tissue (Scotland) Act 2006.

Subhead 2 provides that spouses and civil partners are not designated family members if the couple have been permanently separated or one partner has deserted the other.

Subhead 3 provides that the relationships in Subhead 1 are ranked in the order in which they appear, and that relationships of half-blood may be considered as relationships of full blood for the purposes of determining a person's place in the hierarchy.

Subhead 4 provides that when seeking consent, or confirmation that there is no objection to deemed consent, from a designated family member, consent should be sought from the person who ranks highest on the hierarchy, subject to the exceptions in subhead 6.

Subhead 5 provides that when two people fall within the same paragraph in subhead 1 (e.g. two siblings or two parents) that they are of equal rank. Consent can be given by any individual at that rank.

Subhead 6 provides that where people of equal rank disagree, the family members will be asked to seek a consensus agreement. It is proposed to provide guidance to procurement staff on dealing with cases where there is disagreement between individuals of equal rank. If no such agreement can be reached, then the activity in question will not proceed.Subhead 7 provides for circumstances where a person will be left off the hierarchy:

- persons under 18;
- persons who do not wish to make a decision;
- persons who are unable to make a decision;
- persons cannot reasonably be contacted within the time available;
- persons whose relationship with the adult is not known;

can be left off the hierarchy and a person further down the hierarchy can be considered a designated family member.

Part 2 – Transplantation

Head 7 Interpretation

(1) In this Part, removal of organs for the purposes of transplantation and tissue for the purposes of human application does not include the removal of blood or blood components as defined by the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations, 2005 (S. I. No 360 of 2005).

(2) In this Part, "tissue" does not include an organ, or any tissue removed for the purposes of assisted human reproduction as provided for by the Assisted Human Reproduction Bill 2017..

(3) In this part:

"donation" means donation of human organs for transplantation or tissue for human application;

"domino organ transplant operation" means a transplant 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 or part of an organ into the person; and by so doing, necessitates the removal of an organ or part of an organ from the person which in turn, is intended to be used for transplantation in respect of another living person;

"deemed consent" means that an adult is presumed to have consented to donate their organs after death if they have not registered their objection to becoming an organ donor on the Organ Donation Opt-Out Register;

"non-direct altruistic donation" means donation from an adult living donor who wishes to donate an organ to an individual neither named nor specified by the donor;

"ODTI" means Organ Donation and Transplant Ireland of the HSE, who are the competent authority for organ donation and perform the functions assigned to the HSE under S.I. 325 of 2012;

"procurement organisation" means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the HPRA in accordance with S.I. 325 of 2012 or S.I 158 of 2006;

"removal" means removal for the purposes of transplantation or human application;

"tissue establishment" means a tissue bank or a unit of a hospital or any other body where activities of donation, procurement, testing, processing, preservation, storage or distribution of human tissues are undertaken, and which is authorised to do so by the HPRA in accordance with S.I. 325 of 2012;

"transplantation centre" means a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs and is authorised to do so by the HPRA in accordance with S.I. 325 of 2012.

Explanatory Note

The purpose of this Head is to clarify the type of human material which comes within the ambit of the transplantation provisions in the Act, and which does not.

Subhead 1 excludes blood, blood components and blood products from this Part of the Act. These are regulated by S.I. No 360 of 2005 (European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005) The S.I. regulates the collection and testing of blood or blood components whatever their intended purpose, and the processing, storage and distribution of blood and blood components when they are intended to be used for transfusion. The S.I. does not apply to blood stem cells, which are considered tissue for the purposes of this Act.

Subhead 2 excludes organs from the definition of tissue in this Part of the Act. The subhead also excludes any tissue removed for the purposes of assisted human reproduction, as this will be regulated under the Assisted Human Reproduction Bill 2017. It is not intended to exclude any novel transplants such as ovarian transplants that may occur in the future.

Subhead 3 contains definitions of other key terms used in this Part.

The concept of "deemed consent" is strictly for the purposes of this Part (Transplantation). "Deemed consent" applies specifically in cases of deceased organ donation by an adult where the adult has not registered their objection to becoming an organ donor on the Organ Donation Opt-Out Register, and applies only to the deceased donation of particular organs (see Head 10).

Head 8 Transplantation activities

(1) The following are transplantation activities for the purposes of this Act:

a. removing organs from the body of a living or deceased person for the purposes of transplantation;

b. removing tissue from the body of a living or deceased person for the purposes of human application;

c. maintaining the body of a deceased person for use for the purpose of removing organs for transplantation or removal of tissue for human application;

d. supporting any organs and tissue removed from the body of a living or deceased person for the purposes of transplantation or human application;

e. using, for the purposes of transplantation or human application, any organs or tissue removed from a living or deceased human body.

(2) No person may carry out an activity referred to in subhead (1) except with the appropriate consent required under this Act.

(3) Transplantation activities are lawful if done in the State:

a. with deemed consent in respect of a deceased adult where deemed consent applies and where there is no objection from a designated family member (see Head 10).

b. with consent from a designated family member in respect of a deceased adult when the deceased adult is not registered on the Opt-Out register, and deemed consent does not apply (see Heads 10, 11 and 19);

c. with consent from a parent or guardian in respect of a deceased child (See Head 12);

d. with consent from a living adult donor (see Heads 13, 14, 15 and 16) in respect of donation of organs or tissue;

e. with consent from a parent or guardian, and with the approval of an independent panel, in respect of the donation of regenerative tissue by a living child (see Head 17);

f. with consent from a designated family member, or by a person appointed as a decision-making assistant, co-decision-maker, decision-making representative or person with enduring power of attorney under the Assisted Decision making (Capacity) Act 2015, and with the approval of an independent panel, in respect of the donation of regenerative tissue by an adult who lacks capacity (see Head 18); or

(4) A transplantation activity of the kind mentioned in Subhead (1)(c) or (d) is lawful (without the need for additional consent) where done in the State if:

a. the relevant material has been imported into the State from outside the State;

b. removal of the relevant material from a person's body took place outside the State;

c. appropriate consent was received by the relevant authorities in the State other than this State where the removal took place; and

d. procurement of the relevant material meets the legal requirements of the country of origin, where those legal requirements should be of a similar standard to those in effect in Ireland.

(6) Organs and tissues of a deceased person may be removed for the purposes of transplantation or human application if the person has been certified dead, subject to appropriate consent being in place.

(7) The person certifying the death of a person shall not be the same person who participates directly in the removal of organs or tissues from the deceased person or subsequent transplant procedures, or has responsibilities for the care of potential recipients.

(8) Where a person knows, or has reason to believe, that an examination of the body is, or may be, required by the coroner, the person may not remove organs or tissue (or authorise another person to remove organs or tissue), for the purposes of transplantation or human application, until the Coroner has confirmed that examination of the body is not required to enable the coroner to fulfil his functions under the Coroners Act 1962.

(9) For the purposes of subhead (7) the coroner's confirmation may be given verbally but must be confirmed in writing as soon as is practicable.

(10) The Minister may approve, adopt, or develop guidelines on any matter which comes within the scope of this Part.

Explanatory Note

Subhead 1 defines the range of activities that will be considered "transplant activities" under the Act.

Subhead 2 provides that no such activities may take place without the consent required under the Act.

Subhead 3 describes the type of consent that is required for different transplant activities, as outlined in tables 1 & 2 below.

Table 1: Consent Required for Deceased Donation of Organs/Tissues

	Potential Donor	Donation of:	Consent required:	Head
1.	Deceased adult (other than 2,3,4 or 5)	Liver, Pancreas, Heart, Lungs or Kidney	Deemed Consent, subject to no objection from Designated Family Member.	Head 10
		All other organs/tissues	Consent from Designated Family Member. (Deemed consent does not apply)	Head 11
2.	Deceased adult who has opted-out of organ donation.	None.	**Prohibited**. Family will not be approached to discuss organ donation.	Heads 10 & 19
3.	Deceased adult who is ordinarily resident for less than 12 months	All organs/tissues	Consent from Designated Family Member. (Deemed consent does not apply)	Head 11
4.	Deceased adult who lacks capacity	All organs/tissues	Consent from Designated Family Member (Deemed Consent does not apply)	Head 11
5.	Deceased adult who cannot be identified	All organs/tissues	Deemed consent does not apply	Head 11
6.	Deceased child	All organs/tissues	Consent from parent/guardian (Deemed consent does not apply)	Head 12

Table 2: Consent Required for Living Donation of Organs/Tissues.

	Potential Donor	Donation of:	Consent required:	Head
1.	Adult	Organs/Tissues	Consent from the Adult	Head 14
		Non-directed altruistic donation of organs/tissues	With consent from the adult and approval from the independent panel.	Heads 15 & 16
2.	Child	Organs	**Prohibited**	Head 17
		Regenerative Tissue	With consent from a parent/guardian, and approval from the independent panel.	Heads 15 &17
3.	Adult Who lacks Capacity	Organs	**Prohibited**	Head 18
		Regenerative Tissue	With consent from a designated family member or appropriate person appointed under the Assisted Decision Making (Capacity) Act 2015 and approval by the independent panel.	Heads 15 & 18

Subhead 4 provides that where an organ or tissue has been imported into the State for the purposes of transplantation the appropriate consent must have been received from transplant authorities in the country of origin only. The legal requirements of the country of origin must be met, and these requirements should be of a similar standard to Irish law.

Subhead 6 provides that the organs or tissue of a deceased person can be removed once the person has been certified dead, if appropriate consent is also in place. This subhead is intended to ensure that a medical professional has made a diagnosis of death before transplantation proceeds. It is not proposed to specify criteria for the determination of death in the General Scheme.

It is intended that a person's organs can be donated following brain stem death (DBD) or following cardiac death (DCD).

Brain stem death is the permanent loss of function of the brain stem and this is ascertained through tests carried out to determine the absence of brain function. When these tests show that there is no brain function and no chance of recovery, the patient is declared dead. Donation after Circulatory Death (DCD) (also known as "donation after cardiac death" or "non-heart-beating donation") refers to the retrieval of organs for the purpose of transplantation from patients whose death is diagnosed and confirmed using cardio-respiratory criteria. In order to be considered for DCD, a patient must be dependent upon ventilation or vasopressors to the extent that they are likely to die within 90 minutes of withdrawal of life sustaining measures. Circulatory death is determined following a period of five minutes with zero cardiac activity.

In both cases, determination has been made that death is permanent and irreversible and there is no hope of recovery. Agreement is reached between physicians and family to withdraw end of life care. Any decision to withdraw care is made prior to, and independently of, any decision surrounding organ/tissue donation.

Subhead 7 provides that the same person who certifies the death cannot participate directly in the removal of organs or tissue from the deceased, participate directly in the subsequent transplant procedure, or have responsibility for the care of the recipients. This prohibition is intended to protect against premature certification of death by medical professionals with an interest in retrieving organs for the benefit of another patient. The phrase "directly participates" refers to the surgeons performing the operation, and is not intended to refer to nurses, anaesthesiologists, or intensivists.

Subhead 8 provides that if a person believes, or has reason to believe, that a body may need to be examined by the coroner, then tissues or organs may not be removed from the body until the coroner confirms that the body is not required to fulfil their duties under the Coroner's Act 1962.

Subhead 8 allows for the coroner to provide their confirmation orally for the purposes of subhead 8.

Subhead 10 allows the Minister to make regulations in relation to this Part of the Act.

Head 9 Conditions on consent for organ or tissue donation

(1) Consent for transplant activities may be given:

a. in writing, witnessed by at least one other person; or

b. in cases where the person cannot provide written consent due to a temporary or permanent disability, consent may be given orally, observed by two witnesses, who will testify in writing that the consent was given.

(2) Consent for the removal of organs or tissue from a person for the purposes of transplantation or human application cannot be withdrawn once the retrieval process has begun. This condition must be drawn to the attention of the person giving consent by the procurement organisation when consent is sought.

(3) The person who is requested to consent to organ or tissue donation must be:

a. given sufficient information to understand what the transplantation activities will entail, in line with guidelines drawn up by the Minister;

b. be informed of the type of information that is available to them in respect of the transplantation activities and of their entitlement to receive this information either before or after consent is sought;

c. be provided with whatever information is reasonably requested either before or after the transplantation activities take place.

(4) A copy of the written consent or the witnessed oral consent must be maintained on the donor's medical records, in the hospital department where the organs or tissue procurement is carried out and in the transplant centre. A copy must be offered to the person giving the consent, and must be provided to the person on request.

(5) Consent given for organ donation does not automatically confer consent for secondary activities, including research.

Explanatory Note

Subhead 1 provides that consent for transplant activities may be given in writing, witnessed by at least one other adult. If a person is unable to give consent in writing due to a permanent or temporary disability, consent may be given orally, witnessed by two adults.

Subhead 2 provides that consent cannot be withdrawn once the retrieval process has begun and this should be brought to the attention of the decision maker.

Subhead 3 provides that individuals must be given enough information to allow them to make an informed decision in relation to transplantation. They must be made aware of the range of information available to them and they must be provided with this information on request before and/or after the procedure.

Subhead 4 states that a copy of the consent should be kept on the deceased's medical records and by the hospital department where the organs or tissue are procured and the transplant centre where the transplant operation takes place. A copy must also be made available to the person giving the consent.

Subhead 5 provides that consent given for organ donation does not automatically confer consent for research or other secondary activities.

Head 10 Conditions on deemed consent for deceased organ donation

(1) Deemed consent applies to the donation of organs by all adults who have not registered their objection to becoming an organ donor on the Organ Donation Opt-Out Register (See Head 19), except:

a. those who have not been ordinarily resident in Ireland for at least 12 months prior to death;

b. those who, for a significant period of time before their death, lacked capacity to understand that consent could be deemed if they do not register their objection to becoming a donor on the Opt-Out Register; or

c. people who cannot be identified and/or whose designated family member cannot be contacted.

(2) If it cannot be determined if the exceptions in Subhead (1) apply to the deceased adult, consent from a designated family member under Head 11 must be sought.

(3) The organs of a deceased adult, who has not registered their objection to becoming a donor under Head 19, will not be used for transplantation before a designated family member has been contacted.

(4) The organs of a deceased adult will not be used for transplantation if a designated family member objects to the organ donation.

(5) The designated family member(s) must confirm that they have no objection to the donation taking place:

a. in writing, witnessed by at least one other person; or
b. orally, observed by two witnesses, who will testify in writing that no objection was made.

A copy of this confirmation must be maintained on the deceased's medical records, as well as in the hospital department where the organ procurement is carried out and in the transplant centre. A copy must also be offered to the designated family member of the donor, and must be provided to the person on request.

(6) An objection to organ donation by a designated family member cannot be made once the organ retrieval process has begun. This condition must be brought to the attention of the designated family member before they confirm that they do not object to organ donation.

(7) Deemed consent applies only to the donation of liver, lungs, pancreas, heart, and kidney. For donation of any other tissue or organs, consent from a designated family member under Head 11 must be sought.

Explanatory Note
This Head sets out the conditions under which deemed consent will apply.

Subhead 1 provides that deemed consent will apply to all adults who *do not* record their objection on the register, except those who are not ordinarily resident in Ireland, those who lack capacity, and/or those who cannot be identified or whose designated family member cannot be contacted.

Subhead 2 provides that if it cannot be determined that a person meets the criteria for deemed consent to apply, then consent from a designated family member (see Head 11) must be sought.

Subhead 3 provides that if a person is not on the Opt-Out Register, their designated family member will be consulted prior to the removal of organs.

Subhead 4 provides that if a family member objects to the donation, then deemed consent will not apply and the deceased adult's organs will not be used for transplantation.

Subhead 5 provides that when a designated family member does not object to organ donation, they must confirm their lack of objection in writing, witnessed by one other person. If they cannot write due to a temporary or permanent disability, they must confirm their lack of objection orally, in the presence of two witnesses. Where a family member does not object to the donation, a record of the designated family member's decision must be maintained on the deceased's medical records, in the hospital where the procurement occurs, and in the transplant centre.

Subhead 6 provides that a designated family member cannot object to organ donation once the organ retrieval process has begun and that this provision must be brought to the attention of the designated family member.

Subhead 7 provides that deemed consent only applies to the donation of liver, lungs, pancreas, heart, and kidney. For the donation of other tissues and organs, consent must be sought from a designated family member.

Head 11 Consent for organ or tissue donation given by a designated family member in respect of a deceased adult where deemed consent does not apply

(1) A person shall not remove any organ or tissue from the body of a deceased adult to whom deemed consent does not apply (see Head 10) without consent from a designated family member (see Head 6), given in accordance with Head 9.

(2) Consent to the removal of organs or tissues from a deceased adult for the purposes of transplantation or human application cannot be withdrawn once the retrieval process has begun. This condition must be drawn to the attention of the person giving consent by the procurement organisation when permission is sought.

(3) A copy of the written consent or the witnessed oral consent must be maintained on the deceased's medical records, as well as in the hospital department where the organs or tissue procurement is carried out and in the transplant centre. A copy must also be offered to the designated family member giving the consent.

Explanatory Note

Subhead 1 provides that the adult's designated family member must give consent for organ or tissue donation where deemed consent does not apply. Deemed consent does not apply to those who are not ordinarily resident in Ireland, those who lack capacity, and/or those who cannot be identified or whose designated family member cannot be contacted

Subhead 2 provides that consent cannot be withdrawn once the organ/tissue retrieval process has begun. This condition must be brought to the attention of the decision maker prior to their giving consent.

Subhead 3 provides that a record of the consent must be placed on the deceased medical records, in the hospital where the procurement takes place, and in the transplant centre. A copy must also be made available to the designated family member of the deceased.

Head 12 Consent for organ or tissue donation given by a parent or guardian in respect of a deceased child

(1) A person shall not remove any organ or tissue from the body of a deceased child for the purposes of transplantation or human application without the consent of a parent or guardian of the child, given in accordance with Head 9.

(2) Consent to the removal of organs or tissues from a deceased child for the purposes of transplantation or human application cannot be withdrawn once the retrieval process has begun. This condition must be drawn to the attention of the person giving consent by the procurement organisation when permission is sought. If prior to the removal of any organ or tissue for donation, one parent or guardian objects to the consent given under subhead (1) then that consent has no effect.

(3) A parent of a deceased child who is themselves under 18 may consent to the removal of organs or tissue from their deceased child for the purposes of transplantation.

Explanatory Note
This Head outlines the conditions where organ and tissue donation in respect of a deceased child under 18 is permitted.

Subhead 1 provides that consent may be given by one parent or guardian.

Subhead 2 provides that consent cannot be withdrawn once the organ/tissue retrieval process has begun. This condition must be brought to the attention of the decision maker prior to their giving consent. Any consent ceases to have effect if the other parent or guardian objects to the removal of the organ or tissue for donation.

Subhead 3 provides for a parent who is themselves under eighteen to consent to organ or tissue donation in respect of their child's organs or tissue.

Head 13 Conditions on donation of organs by living adults

(1) An organ of a living adult may be removed for the purposes of transplantation if the following requirements are met:

a. consent has been given, in accordance with Head 9, by the adult;

b. there is no evidence of duress or coercion in relation to the donation;

c. the transplantation is solely for the therapeutic benefit of the recipient;

d. there is no alternative therapeutic intervention of comparable effectiveness;

e. the donation has the potential to be life-saving for the recipient;

f. the donor has not and will not receive any monetary compensation or other non-financial inducements for donating their organ.

(2) The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of income related to the donation in accordance with S.I. 325 of 2012.

(3) The transplant centre shall offer access to independent advice on the consequences and risks which may be associated with the removal of the organ to the donor. The advice will be provided by an appropriately qualified and experienced health care professional who is not involved in either the removal or transplantation of the organ.

(4) The donor may freely withdraw consent at any time up to the time of removal of the organ.

Explanatory Note

This Head sets out the requirements for the donation of organs by living adult donors. This Head provides for donation for transplantation by living adults and includes direct donation to a known recipient (i.e. a relative or close friend), paired kidney exchange, or domino paired exchange.

A paired kidney exchange occurs when a living kidney donor is incompatible with the recipient, and so exchanges kidneys with another donor/recipient pair.

A domino paired exchange allows multiple pairs of donors/recipients to benefit from transplant. Subhead 1 provides that consent must have been given by the donor in accordance with Head 9. There must be no evidence of coercion or duress upon the donor. The transplant must be purely for the therapeutic benefit of the recipient, and there must be no alternative treatment of comparable effectiveness. The donation must have the potential to be life saving for the recipient. The donor may not receive any financial or non-financial inducements for donating their organ.

Subhead 2 makes an exception to the non-payment principle above, allowing for living donors to receive compensation for expenses and loss of income. This provision is in accordance with S.I. 325 of 2012, European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012.

Subhead 3 provides that a transplant centre must also provide information to the donor on all the potential risks associated with organ donation, and that information must be provided by a suitably qualified professional who is independent of the transplant operation.

Subhead 4 provides that the donor may withdraw consent at any time up until the removal of the organ.

Additional requirements must be met before a person can donate to a person who is not known to them (also known as “altruistic donation”). These conditions are specified in Head 16.

Head 14 Conditions on donation of tissues by living adults

(1) The tissue of a living adult may be removed for the purposes of human application if the following requirements are met:

a. consent has been given, in accordance with Head 9, by the adult;

b. there is no evidence of duress or coercion in relation to the donation;

c. the donation is solely for the therapeutic benefit of the recipient;

d. the donor has not and will not receive any monetary compensation or other non-financial inducements for donating their tissue;

e. the principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and inconveniences related to the donation in accordance with section 13(4) of S.I. 158 of 2006.

(2) The tissue establishment shall offer access to independent advice on the consequences and risks which may be associated with the removal of the tissue to the donor. The advice will be provided by an appropriately qualified and experienced health care professional who is not involved in either the removal or transplantation of the tissue.

(3) The donor may freely withdraw consent at any time up to the time of removal of the tissue.

Explanatory Note

This Head sets out the requirements for the donation of tissue by living adult donors.

Subhead 1 provides that consent must have been given by the donor in accordance with Head 9. There must be no evidence of coercion or duress upon the donor. The donation must be purely for the therapeutic benefit of the recipient. The donor may not receive any financial or non-financial inducements for donating their tissue, either prior to or after the transplantation, except to compensation for expenses and inconveniences related to the donation. This provision is in accordance with section 13(4) of S.I. 158 of2006, S.I. No 158 of 2006 (European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006).Subhead 2 provides that a tissue establishment must also provide information to the donor on all the potential risks associated with the donation, and that information must be provided by a suitably qualified professional who is independent of the transplant operation.

Subhead 3 provides that the donor may withdraw consent at any time up until the removal of the tissue.

Head 15 Independent panel for certain cases of living donation of organs and/or tissue

(1) The Minister shall appoint an independent panel of suitable persons to consider applications for living organ and tissue donation under the following circumstances:
    a. donation of an organ from a non-direct altruistic donor under Head 16;
    b. donation of tissue from a child under Head 17;
    c. donation of tissue from an adult who lacks capacity under Head 18;

(2) Panel members:
    a. shall be appointed for such a period of time as the Minister may determine;
    b. may be paid such expenses, with consent of the Minister for Public Expenditure and Reform, as the Minister may from time to time determine;
    c. may at any time be removed from the panel by the Minister for stated reasons;
    d. may resign at any time;

(3) The independent panel must include representation from an ethicist, a legal practitioner, an independent physician and a psychiatrist.

(4) The independent panel shall be independent and impartial in the carrying out of their functions.

(5) The HPRA shall furnish such support of an administrative nature to the independent panel as the HPRA consider necessary to enable the panel to perform its functions.

Explanatory Note

This Head provides for the Minister to establish an independent panel which will authorise living donation of organs and tissues in certain cases which require additional safeguards to protect the potential donor.

The independent panel must authorise:

- donation of an organ from a non-direct altruistic donor;
- donation of tissue from a child; and
- donation of tissue from an adult who lacks capacity.

Subhead 2 provides that panel members are appointed by the Minister. The Minister may determine the length of appointment, any expenses payable to the panel members and any other terms or conditions that apply to membership. This subhead also provides that the Minister may remove a member for stated reasons, and that members may resign at any time.

Subhead 3 provides that the panel must include an ethicist, a legal practitioner, an independent physician, a psychiatrist. This is intended to ensure that the panel has a minimum level of expertise in fields pertinent to decisions regarding organ donation.

Subhead 4 provides that the panel shall be impartial and independent in carrying out its functions

Subhead 5 provides that the HPRA will provide administrative support to the panel as required.

Head 16 Conditions on donation of organs by non-direct altruistic donors

(1) An organ or part of an organ of a non-direct altruistic donor may be removed for the purposes of transplantation if the following requirements are met:

a. consent has been given, in accordance with Head 9, by the adult;

b. there is no evidence of duress or coercion in relation to the donation;

c. the transplantation is solely for the therapeutic benefit of the recipient;

d. there is no alternative therapeutic intervention of comparable effectiveness;

e. the donation has the potential to be life-saving for the recipient; and

f. the donor has not and will not receive any monetary compensation or other non-financial inducements for donating their organ.

(2) The principle of non-payment shall not prevent non-direct altruistic donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of income related to the donation in accordance with S.I. 325 of 2012.

(3) The donation must be approved by the independent panel established under Head 15.

(4) An application to the independent panel for approval under subhead (3) shall be made in the form required by the independent panel, by the transplant centre which is proposing to remove the organ.

(5) On receipt of an application under subhead (5), the independent panel shall arrange for a suitably qualified person to prepare a report to it on the matters referred to in paragraphs (a) to (f) of sub head (1). A copy of the report shall be kept on the donor's medical records and in the transplant centre.

(6) The independent panel may approve an application under subhead (5) where it is satisfied that:

a. there is no evidence that the motivation for the donation is monetary compensation or other non-financial inducements for donating their organ;

b. the donation has the potential to be life-saving for a recipient;

c. there is no alternative therapeutic intervention of comparable effectiveness; and

d. any other conditions which may be specified in regulations made under this Act by the Minister are satisfied.

(7) In considering an application under subhead (5), the independent panel shall have regard to the report from the person referred to under subhead (5).

(8) The independent panel shall not appoint a person under subhead (5) unless it is satisfied that the person has no connection with:

a. the donor;

b. the recipient of the organ; or

c. the transplantation centre;

which could be considered by a reasonable person to be of a kind that might raise doubts about the ability of that person to act impartially.

(9) The transplant centre shall offer access to independent advice on the consequences and risks which may be associated with the removal of the organ to the non-direct altruistic donor. The advice will be provided by an appropriately qualified and experienced health care professional who is not involved in either the removal or transplantation of the organ.

(10) The non-direct altruistic donor may freely withdraw consent at any time up to the time of removal of the organ.

(11) The non-direct altruistic donor cannot direct that the organ must be donated to a person of a particular race, religion, sex or sexual orientation.

Explanatory Note

This Head sets out the conditions that must be met before a person can donate to a person who is not known to them (also known as "altruistic donation"). Altruistic donors make a donation to the transplant pool, but do not direct their donation to a specific person.

Subhead 1 provides that consent must have been given by the donor in accordance with Head 9. There must be no evidence of coercion or duress upon the donor. The transplant must be purely for the therapeutic benefit of the recipient, and there must be no alternative treatment of comparable effectiveness. The donation must have the potential to be life saving for the recipient. The donor may not receive any financial or non-financial inducements for donating their organ.

Subhead 2 makes an exception to the non-payment principle above, allowing for living donors to receive compensation for expenses and loss of income. This provision is in accordance with S.I. 325 of 2012, European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012.

In a case of altruistic donation, further conditions must be met before an organ can be removed for transplantation. Subheads 3-8 set out these conditions. An application for approval must be made to the independent panel established under Head 15.

In order to approve a donation of tissue, the independent panel must be satisfied that:

- there is no evidence of duress or coercion in respect of the donation;
- the donation has the potential to be life saving for the recipient; and
- there is no other intervention of comparable effectiveness.

The Minister may add additional conditions to govern this type of donation.

After an application is made to the independent panel, a suitably qualified individual who is independent of the transplant operation must prepare a report on these matters, which will be considered by the panel before giving their approval.

Subhead 9 provides that the transplant centre must also provide information to the donor on all the potential risks associated with organ donation, and that information must be provided by a suitably qualified professional who is independent of the transplant operation.

Subhead 10 provides that the donor may withdraw consent at any time up until the removal of the organ.

Subhead 11 states that the donor cannot direct their donation to a person on the basis of race, gender, sexual orientation or religion.

Head 17 Conditions on donation of organs and tissues by living children

(1) An organ may not be removed from a living child for the purposes of transplantation.

(2) Subhead (1) does not apply to the removal of an organ that:
   a. during a domino organ transplant operation, is necessarily removed from a child; and
   b. is in turn intended to be used for transplantation of another living person.

(3) A person shall not use an organ for transplantation purposes that has been removed from a living child during a domino transplant without consent from a parent or guardian.

(4) A person shall not remove regenerative tissues from a living child for the purposes of donation unless consent has been given, in accordance with Head 9, by at least one parent or guardian, and approval for the removal has been given by the independent panel established in Head 15.

(5) An application to the independent panel for approval under subhead (4) shall be made, in the form required by the independent panel, by the tissue establishment which is proposing to remove the tissue.

(6) On receipt of an application under subhead (5), the independent panel shall arrange for a suitably qualified person to prepare a report to it on the matters referred to in paragraphs (a) to (i) of subhead 7. A copy of the report shall be kept on the donor's medical records and in the transplant centre.

(7) The independent panel may approve an application under subhead (5) where it is satisfied that:

   a. consent has been given under Subhead (4), by at least one parent or guardian;

   b. subject to paragraph (b) of subhead (8), where possible, the child assents to the donation;

   c. there is no evidence of duress or coercion in relation to the donation;

   d. the parent or guardian, and subject to the capacity of the donor to understand such information, the donor, have been given sufficient information as to the nature of the medical procedure for, and the risk involved in, the removal of the tissue in question by a person who is qualified to give that information;

   e. the donation has the potential to be life-saving for the recipient;

   f. the recipient is a close relative of the donor;

   g. there is no compatible donor available who has the capacity to consent;

   h. there is no alternative therapeutic intervention of comparable effectiveness; and

   i. any other conditions which may be specified in regulations made under this Act by the Minister are satisfied.

(8) In considering an application under subhead (5), the independent panel shall have regard to:

   a. the report from the person referred to under subhead (6); and

b. the opinion of the donor as an increasingly determining factor in proportion to his or her age, degree of maturity and decision-making competence in relation to the making of a decision in respect of the donation.

(9) If one parent or guardian objects in writing to the consent given under sub-head 7(a) then that consent is not valid.

(10) A parent or guardian may withdraw consent at any time up to the time of removal of the tissue.

Explanatory Note

Subheads 1 and 2 state that organs, or parts of organs, may never be removed from a child for the purposes of transplantation, unless that organ must be removed as part of a domino transplant operation and is intended for use for transplantation into another living person.

In a case of donation of regenerative tissue by living children, further conditions must be met before regenerative tissue can be removed for transplantation. Subheads 3-8 set out these conditions. Before tissues can be removed from a child for the purposes of human application, approval must be gained from the independent panel established in Head 15.

In order to approve a donation of regenerative tissue, the independent panel must be satisfied that:

- a parent/guardian has consented to the procedure; and
- the child assents as much as is possible given their age, maturity, and decision making capacity. It is intended that children of any age may donate regenerative tissue. If the child is too young to give assent, then subhead 7(b) does not apply.

The panel must also be satisfied that:

- there is no evidence of duress or coercion in respect of the donation;
- the parents/guardians and the donor have been given sufficient information to understand the risks of the procedure;
- the donation has the potential to be life saving for the recipient;
- the recipient is a close relative of the donor (e.g. parent, child, sibling); and
- there is no other donor with the capacity to consent; and that there is no other intervention of comparable effectiveness.

The Minister may add conditions in respect of this type of donation. After an application is made to the independent panel, a suitably qualified individual who is independent of the transplant operation must prepare a report on these matters, which will be considered by the panel before giving their approval.

Subheads 9 & 10 provide that if one parent or guardian objects in writing to the giving of consent for such a procedure, then the consent is not valid. A parent or guardian can withdraw consent at any time up until the removal of tissue.

Head 18 Conditions on donation of organs and tissues by living adults who lack capacity

(1) An organ may not be removed, from a living adult who lacks capacity, for the purposes of transplantation.

(2) Subhead (1) does not apply to the removal of an organ that:

a. during a domino organ transplant operation, is necessarily removed from an adult who lacks capacity; and

b. is in turn intended to be used for transplantation of another living person.

(3) A person shall not use an organ for transplantation purposes that has been removed from a person who lacks capacity during a domino transplant without consent from a designated family member, or by a person appointed as a decision-making assistant, co-decision-maker, decision-making representative or person with enduring power of attorney under the Assisted Decision making (Capacity) Act 2015.

(4) A person shall not remove tissues from a living adult who lacks capacity for the purposes of donation unless consent has been given, in accordance with Head 9, a designated family member, or by a person appointed as a decision-making assistant, co-decision-maker, decision-making representative or person with enduring power of attorney under the Assisted Decision making (Capacity) Act 2015, and approval for the removal has been given by the independent panel established in Head 15.

(5) An application to the independent panel for approval under subhead (4) shall be made, in the form required by the independent panel, by the tissue establishment which is proposing to remove the tissue.

(6) On receipt of an application under subhead (5), the independent panel shall arrange for a suitably qualified person to prepare a report to it on the matters referred to in paragraphs (a) to (i) of subhead (7). A copy of the report shall be kept on the donor's medical records and in the transplant centre.

(7) The independent panel may approve an application under subhead (5) where it is satisfied that:

a. consent has been given, under subhead (4), by a designated family member, or by a person appointed as a decision-making assistant, co-decision-maker, decision-making representative or person with enduring power of attorney under the Assisted Decision-Making (Capacity) Act 2015;

b. subject to paragraph (b) of subhead (8), the adult who lacks capacity assents to the donation;

c. there is no evidence of duress or coercion in relation to the donation;

d. the person(s) being asked for consent and, subject to the capacity of the donor to understand such information, the donor, have been given sufficient information as to the nature of the medical procedure for, and the risk involved in, the removal of the tissue in question by a person who is qualified to give that information;

e. the donation has the potential to be life-saving for the recipient;

f. the recipient is a close relative of the donor;

g. there is no compatible donor available who has the capacity to consent;

h. there is no alternative therapeutic intervention of comparable effectiveness; and

i. any other conditions which may be specified in regulations made under this Act by the Minister are satisfied.

(8) In considering an application under subhead (4), the independent panel shall have regard to:

a. the report from the person referred to under subhead (6); and

b. the opinion of the donor as an increasingly determining factor in proportion to his or her decision-making competence in relation to the making of a decision in respect of the donation.

(9) The person(s) who gave consent, or subject to their capacity, the donor may withdraw consent at any time up to the time of removal of the tissue;

Explanatory Note

Subheads 1 & 2 state that organs, or parts of organs, may never be removed from a living adult who lacks capacity for the purposes of transplantation, unless that organ must be removed as part of a domino transplant operation and is intended for use for transplantation into another living person.

Subheads 3-7 also set out the requirements for the donation of regenerative tissues by adults who lack capacity. Before regenerative tissues can be removed from an adult who lacks capacity for the purposes of transplantation, approval must be gained from the independent panel established in Head 15.

In order to approve a donation of regenerative tissue, the panel must be satisfied that:

- consent has been given by a designated family member, or by a person appointed as decision-making assistant, co-decision-maker, decision-making representative or person with enduring power of attorney under the Assisted Decision-Making (Capacity) Act 2015. This provision is intended to be compatible with the Assisted Decision-Making (Capacity) Act. The Act makes provision for individuals to assist a person whose capacity may be in question, or may shortly come into question;
- the donor assents as much as is possible given their decision making capacity; there is no evidence of duress or coercion in respect of the donation;
- the person giving consent and the donor have been given sufficient information to understand the risks of the procedure; that the donation has the potential to be life saving for the recipient;
- the recipient is a close relative of the donor (a parent, child, or sibling); and
- there is no other donor with the capacity to consent; and that there is no other intervention of comparable effectiveness. The Minister may add conditions in respect of this type of donation.

Subhead 8 provides that after an application is made to the independent panel, a suitably qualified individual who is independent of the transplant operation must prepare a report on these matters, which will be considered by the panel before giving their approval.

Subhead 9 provides that consent can be withdrawn by the person who gave consent at any time up until the removal of tissue.

Head 19 Organ Donation Opt-Out Register

(1) The ODTI shall establish an Organ Donation Opt-Out Register.

(2) All adults may register their objection to becoming an organ donor on the Opt-Out Register.

(3) An entry under subhead (2) shall also include the following:

a. the adult's name;

b. the adult's date of birth; and

c. the adult's address.

(4) The Minister may prescribe the way in which information under subhead (3) shall be recorded.

(5) An adult may alter their information on the register, or revoke their objection and remove their information from the register at any time.

(6) An entry under subhead (2) shall be maintained for the lifetime of the adult concerned, or until the adult voluntarily removes themselves from the register.

(7) The organs of a deceased person shall not be used for transplantation if a person has registered their objection to becoming an organ donor on the register and that objection has not been revoked at the time of the person's death.

(8) The ODTI will have access to the information on the register. The register shall not be open to public inspection or search.

(9) The ODTI may disclose information from the register to relevant medical staff for the purposes of determining if a designated family member can be approached to discuss organ donation.

(10) A person who receives information under subsection (9) may disclose that information to a designated family member of the person to whom the information pertains when:

a. the person concerned is on the opt-out register and the family member has enquired about organ donation; or
b. the person concerned is not on the opt-out register and deemed consent applies.

(11) The Minister may, by Regulation, develop guidelines for the operation of the Organ Donation Opt-Out Register.

Explanatory Note
Subheads 1 & 2 provide that the Organ Donation Opt-Out Register will be established and maintained by the ODTI. All adults have the option to register their objection to becoming an organ donor after death – to "opt-out" of organ donation.

Subheads 3 and 4 provide that an entry on the register will include the person's name, date of birth, and address, and that the Minister may prescribe the way in which information on the register will be recorded. The intention is to provide for the identification of the person on the register. If Individual Health Identifiers become available, it is proposed that these will be added to the information on the register.

Subhead 5 provides for a person to alter their information on the register, or to revoke their objection and remove their information from the register.

Subhead 6 provides that if a person is on the Opt-Out Register, and they have not revoked their objection at the time of death, their organs will not be donated after death.

Subhead 7 provides that information in an entry on the register will be maintained for the lifetime of the person the entry concerns, or until the person voluntarily removes themselves from the opt-out register.

Subheads 8-10 outline who will have access to the information on the register and to whom information may be disclosed. The ODTI will have access to the information on the register, and the register will not be open to inspection or search by the public. The ODTI may share relevant information with relevant medical staff for the purpose of determining if the deceased person's family members may be approached to discuss organ donation. If an adult is on the opt-out register, their family members will not be approached to discuss organ donation.

The relevant staff will be:

- organ donation nurse managers
- clinical leads on organ donation
- intensivists & intensive care nurses at the donor hospital.

The specified persons can share that information with family members as required:

- when a deceased person is on the opt-out register, their family will not be approached to discuss organ donation. However, if the family enquire about organ donation, it may be disclosed to them that the deceased person had opted out of organ donation.
- when a deceased person is not on the opt-out register and deemed consent applies, this information can be shared with members of the deceased's family to facilitate their making a decision with regard to deemed consent (whether there is an objection to deemed consent).

Subhead 11 allows the Minister to develop guidelines for the operation of the register by regulation.

Head 20 Organ donation to have priority

(1) The procurement of a person's organs for transplantation takes priority over:

a. any consent given in respect of a post-mortem examination; or

b. consent by the individual to donate their body for anatomical examination, or public display;

unless the body is required to enable the coroner to fulfil his functions under the Coroners Act 1962.

Explanatory Note
This Head ensures that consent for organ donation for transplantation will have priority over consent for any other purpose, including post-mortem examination, donation for anatomical examination, or public display. This Head does not apply if the body comes under the jurisdiction of the coroner.

If a person has given consent for the transplantation of organs, or if consent is deemed, then transplant may take place even if consent has been given for some other purpose.

Head 21 Removal of tissue sample to determine viability of transplantation

(1) If it appears to a person removing, in accordance with consent by virtue of Heads 9, 10, 11, or 12, any part of the body of a deceased person for transplantation that it is necessary or expedient to examine tissue sample removed from the part or any other part of the body to determine the viability of the transplantation (including in particular the safety of the transplant for the person who is to receive it), the person carrying out the removal may remove and secure the examination of such tissue sample from the part of the body as the person considers necessary or expedient for that purpose.

Explanatory Note
This Head provides that a person removing any part of the body for transplantation from a deceased person with appropriate consent, may also examine tissue sample removed from the body to determine the viability of the transplant, if it is considered necessary or expedient.

Head 22 Preservation for transplantation activities

(1) Where organs, tissues, or both organs and tissues from a deceased person are, or may be, suitable for procurement for transplantation activities, steps for the purpose of preserving the organs and tissues for procurement for transplantation activities may be taken, and the body may be maintained for that purpose.

(2) Authority under subhead (1) extends only to the taking of reasonable steps necessary for the purpose mentioned in that paragraph.

(3) Authority under subhead (1) will cease to apply once it has been established that there will be an objection to the removal of the part for transplantation.

Explanatory Note
This Head provides that where organs and/or tissues from a deceased person are or may be suitable for transplantation, medical practitioners may take steps to preserve the organs/ tissues for that purpose, and/or to maintain the body for the purpose of preserving organs/tissues for transplantation. This provision only allows reasonable steps to be taken, and this provision ceases to apply if it is established that a designated family member objects to the donation. It is intended to provide guidance to practitioners on what constitutes "reasonable steps".

Head 23 Trafficking in human organs

(1) It is an offence, when committed intentionally, to remove an organ from living or deceased donors:

a. where the removal is performed without the consent of the living donor, or, in the case of the deceased donor, without the removal being subject to deemed consent or consent;

b. where, in exchange for the removal of organs, the living donor, or a third party, has been offered or has received a financial gain or comparable advantage; or

c. where in exchange for the removal of organs from a deceased donor, a third party has been offered or has received a financial gain or comparable advantage.

(2) In this Part "financial gain or comparable advantage" shall not include compensation for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations, or compensation in case of damage which is not inherent to the removal of organs.

(3) A person is guilty of an offence, when they intentionally:

a. remove a human organ from a living or deceased donor outside the HSE "Framework for Quality and Safety of Human Organs Intended for Transplantation" or where the implantation is performed in breach of the provisions of this Act and S.I. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation) regulations;

b. implant a human organ from a living or deceased donor outside of a centre authorised by the HPRA, or where the implantation is performed in breach of the provisions of this Act and S.I. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation) regulations;

c. solicit and recruit an organ donor or a recipient, where carried out for financial gain or comparable advantage for the person soliciting or recruiting, or for a third party;

d. promise, offer or give directly or indirectly, any undue advantage to healthcare professionals, public officials, or persons who direct or work for private sector entities, in any capacity, with a view to having a removal or implantation of a human organ performed or facilitated, where such removal or implantation takes place under the circumstances described in subheads 3(a) and 3(b);

e. prepare, preserve or store illicitly removed human organs as described in subheads 3(a) and 3(b);

f. transport, transfer, receive, import and export illicitly removed human organs as described in subheads 3(a) and 3(b);

g. aid or abet the commission of any of the offences above;

h. intentionally attempt to commit any of the offences above.

(4) A healthcare professional, a public official or any person who directs or works for private sector entities, in any capacity, is guilty of an offence if they request or receive any undue advantage with a view to performing or facilitating the performance of a removal or implantation of a human organ, where such removal or implantation takes place under the circumstances described in subheads 3(a) and 3(b).

Explanatory Note
Subhead 1 makes it an offence to:

- remove an organ without the appropriate consent;
- receive, or offer, a financial reward in respect of a living donation; or
- receive, or offer, a financial reward in respect of a deceased donation.

Subhead 2 provides that the definition of "financial reward of comparable advantage" does not include compensation for loss of earnings or for reasonable expenses incurred due to the transplant procedure or examinations related to the procedure, nor does it include compensation for damages that may arise.

Subhead 3 provides that a person is guilty of an offence when they intentionally:

- remove or implant an organ outside the HSE framework;
- remove or implant an organ outside a centre authorised for transplantation by the HPRA;
- solicit an organ donation for financial gain;
- attempt to give financial advantage to a healthcare professional to perform or expedite an organ donation;
- prepare, preserve, store, transport, transfer, receive, import, or export an organ removed outside of the HSE framework and/or an authorised transplant centre;
- aid or abet any of the above offences; or
- attempt to commit any of the above offences.

Subhead 4 provides that a healthcare professional, public official, or a person directing or working for a private entity, will be guilty of an offence if they request or receive any undue advantage in return for performing or facilitating a transplant outside the HSE framework and/or outside an authorised transplant centre.

Head 24 Designation and functions of the regulator

(1) The Minister may designate, by regulation, a regulator for the consent provisions in this Part of the Act.

(2) The regulator will monitor compliance with the consent provisions in this Part.

(3) The regulator:

a. may appoint one or more persons, as the regulator sees fit, to be authorised officers for the purposes of this Part; and

b. will furnish each authorised officer appointed by it with a warrant of the authorised officer's appointment.

(4) An authorised officer will, when performing a function imposed on an authorised officer under this Part of the Act, produce their warrant for inspection if requested to do so by a person affected by the performance of that function.

(5) The regulator will develop and put in place a system of monitoring and inspections for each site at which transplant activities take place for the purpose of ensuring that the transplant centre complies with the consent requirements of this Part, with regulations made under this Part, and with any standard guidelines determined by the Minister.

(6) The regulator may also serve a notice on a responsible person requiring that they furnish the regulator with such information concerning compliance with this Part, or with regulations made under this Part, within the period of time which may be specified in the notice.

(7) Any person who receives a request for information in accordance with subhead (6) will provide the information requested within the period specified.

Explanatory Note

This Head allows for the Minister to appoint a regulator for the consent provisions in this Part of the Act, and sets out the responsibilities and functions of the regulator.

Subheads 2-4 provide that the regulator will monitor compliance with the provisions of this Part, and provides for the regulator to appoint one or more authorised officers, who will be furnished with a warrant. The authorised person must produce their warrant for inspection when performing duties and functions in accordance with their role.

Subhead 5 provides that the regulator will monitor sites where transplant activities are taking place, to ensure compliance with the consent requirements of this part.

Subheads 6 and 7 provide for the regulator to serve a notice on a responsible person that compels them to provide the regulator with information concerning the transplant centre's compliance with this Act and with regulations made under this Act. A person who receives such a request must provide the information in the time specified.

The ODTI is the competent authority for organ donation, and performs the functions assigned to the HSE under S.I. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation). The HPRA already conducts inspections in relation to transplantation. It is proposed that regulatory duties under this part will be undertaken by the ODTI and the HPRA.

PART 3 – Pathology Practice

Head 25 Post-mortem activities

(1) "Post-mortem activities" in this Part means:

a. A post-mortem examination;

b. the retention, by the hospital where the post-mortem examination took place, of any tissue removed from a deceased person or fetus during a post-mortem examination, excluding the retention of tissue samples in the deceased's medical records;

c. the use of any tissue retained after a post-mortem, including the use of tissue by a third party;

d. the recording of a post-mortem;

e. disposal, burial, or return of any tissue removed as part of a post-mortem, excluding any biological fluids removed as part of the post-mortem examination.

(2) No person may carry out an activity referred to in subhead (1) except with the appropriate consent required under the Act.

(3) A person may not receive payment for tissue that has been removed for the purposes of post-mortem activities, and such tissue cannot be used for commercial purposes.

(4) This Part does not apply to:

a. activities done for purposes of a function of the coroner or under the authority of the coroner under the Coroner's Act 1962; or

b. matters which are connected with the enforcement or administration of law, including activities conducted as part of a criminal investigation or following a criminal conviction.

(5) The Minister may approve, adopt, or develop guidelines on any matter which comes within the scope of this Part.

Explanatory Note

Subhead 1 sets out the range of activities considered "post-mortem activities" for the purposes of this part. "Post-mortem activities" includes the examination itself, as well as the retention of any tissue by the hospital where the examination took place, the use of any tissue retained after a post-mortem by the hospital or a third party, the recording of the post-mortem, and the disposal, burial, or return of any tissue removed in the course of the post-mortem. The retention of tissue as part of the deceased medical records is not considered a "post-mortem" activity for the purposes of this Part.

Subhead 2 provides that no post-mortem activity may be carried out without appropriate consent.

Subhead 3 provides that no payment may be received for tissue removed as part of a post-mortem activity.

Subhead 4 excludes activities performed for the purposes of a function of the coroner or under the jurisdiction of the coroner -). these post-mortems do not require consent and are covered under the Coroner's Act (1962).
Subhead 5 allows the Minister to approve, adopt, or develop guidelines on matters that fall under this Part.

Head 26 Consent for post-mortem activities

(1) Consent for post-mortem activities may be given:

a. by an adult prior to their death;

b. by a designated family member of a deceased adult (see Head 6); or

c. a parent or guardian of a deceased child or fetus.

(2) Consent may be given:

a. in writing, witnessed by at least one other adult; or

b. in cases where the person cannot provide written consent due to a temporary or permanent disability, consent may be given orally, observed by two adult witnesses, present at the same time, who will testify in writing that the consent was given.

(3) A person's consent may be limited to particular post-mortem activities or may limit post-mortem activities to particular tissues and organs.

(4) Consent to a post-mortem activity may be withdrawn prior to a post-mortem examination, by the person who gave consent.

(5) The Minister may make an application to the High Court to make an order allowing a post-mortem activity, without consent, in exceptional circumstances.

(6) Consent given for post-mortem activities does not automatically confer consent for secondary activities, including research.

Explanatory Note
This Head sets out the consent required to undertake post-mortem activities (as defined under Head 25).

Subhead 1 provides an adult may give consent to post-mortem activities prior to their death. After the death of the adult, consent may be given by a designated family member of an adult. In the case of a deceased child or a fetus, a parent or guardian may consent to post-mortem activities.

Subhead 2 provides the forms in which consent may be given. Consent may be given in writing, witnessed by at least one other adult. If a person cannot provide written consent due to a temporary or permanent disability, consent may be given orally, observed by two adult witnesses. The witnesses must be present at the same time, and must be willing to testify in writing that the consent was given.

Subhead 3 provides that the person giving consent for these activities may limit their consent to any subset or combination of activities. "Post-mortem" activities (as defined under Head 25) includes the post-mortem examination itself, but also all related activities involving the

retention, use, and disposal of tissue used in the examination. For example, a person may choose to consent to the examination, but not to any retention of tissue or use by a third party, or they may choose to consent to examination and retention, but not use by a third party, and so on for any combination of post-mortem activities. A person may also limit which tissues and organs may be used in post-mortem activities.

Subhead 4 provides that consent can be withdrawn prior to a post-mortem examination.

Subhead 5 provides that the Minister can apply to the High Court to allow a post-mortem examination to take place without consent in exceptional circumstances, such as when a public health issue may arise.

Subhead 6 provides that consent given for post-mortem activities does not automatically confer consent for research or other secondary activities.

Head 27 Consent by a parent for post-mortem activities for a deceased child

(1) A post-mortem activity must not be taken in relation to a deceased child without the consent of a parent or guardian of the child. In this Head, "deceased child" includes a stillborn child.

(2) A parent or guardian of a deceased child may consent to post-mortem activities.

(3) A parent or guardian of a deceased child who is themselves under 18 may consent to post-mortem activities.

(4) The parent or guardian should have regard to any previously expressed wishes of the child, in proportion to his or her age, degree of maturity and decision-making competence in relation to the making of a decision in respect of the post-mortem activity.

(5) If prior to the removal of any organ or tissue, one parent or guardian objects to the consent given under sub-head (2) then that consent has no effect.

Explanatory Note
This Head sets out the consent required to undertake post-mortem activities (as defined under Head 25) for a deceased child.

Subhead 1 provides that a parent or guardian of a deceased child must give consent before post-mortem activities are performed on the body of the deceased child. For the purposes of this Head "deceased child" includes a stillborn child.

Subhead 2 provides that a parent or guardian may give consent for post mortem activities to take place.

Subhead 3 provides for parents who are themselves under eighteen to provide consent with regard to their children.

Subhead 4 provides that a parent's decision to consent should consider any previously expressed wishes of the child, subject to the child's age and capacity to understand the activities in question.

Subhead 5 provides that if one parent or guardian objects to the consent given for post-mortem activities, then that consent is no longer valid.

Head 28 Consent by a parent for post-mortem activities for a fetus

(1) In this Head, "post-mortem activity" includes a laboratory examination performed on a fetus for any of the purposes outlined under Head 30.

(2) A post-mortem activity must not be taken in relation to a fetus without the consent of a parent of the fetus.

(3) A parent of a deceased fetus may consent to post-mortem activities.

(4) A parent of a deceased fetus who is themselves under 18 may consent to post-mortem activities.

(5) If the parents disagree regarding consent, the wishes of the mother shall be followed.

Explanatory Note
This Head sets out the consent required to undertake post-mortem activities (as defined under Head 25) on a fetus.

Subhead 1 provides that for the purposes of this Head, a laboratory examination performed on a fetus for any of the purposes under Head 30 is considered a "post-mortem activity".

Subheads 2-4 provide that a parent of a fetus must give consent before post-mortem activities are performed on the fetus. Parents who are themselves under eighteen may consent to post-mortem activities.

Subhead 5 provides that if the parents of a deceased fetus disagree regarding consent, the wishes of the mother will take precedence.

Head 29 Process of seeking consent for post-mortem activities

(1) The person who is requested to consent to post-mortem activities must:

a. be given sufficient information to understand what the post-mortem activities entail, in line with guidelines drawn up by the Minister;

b. be given indication of the tissue likely to be removed;

c. be informed of the type of information that is available to them in respect of the post-mortem activities and of their entitlement to receive this information either before or after consent is sought;

d. be provided with whatever information is reasonably requested either before or after the post-mortem activities have taken place;

e. be provided with information on the options available to the subsequent return, burial, disposal or cremation of retained tissue;

f. be given an indication of the length of time the tissue may be retained; and

g. be informed that the post-mortem report may be provided to them at their request.

(2) A copy of the written or witnessed oral consent given in accordance with Heads 26, 27 and 28 must be:

a. kept on the deceased's medical record, or, in the case of a fetus, on the medical records of the mother;

b. kept in the hospital department where the post-mortem examination is carried out; and

c. offered to the person who gave the consent.

(3) Where consent is given for tissue to be removed from the body of a deceased person or fetus during the post-mortem examination, tissue samples:

a. may, by virtue of the consent, be taken from the tissue;

b. if taken, form part of the medical records of the deceased person; and

c. if taken from a fetus, form part of the medical records of the mother.

(4) Accurate and detailed record keeping of all tissue retained, other than tissue samples, must be maintained in the hospital where the post-mortem examination took place, in accordance with guidelines determined by the Minister.

(5) The hospital where the post-mortem examination took place will make a copy of the post-mortem available to the person who gave consent, on their request.

(6) Tissue samples obtained during the course of a post-mortem carried out before the date on which this Part comes into force may be used for post-mortem activities without consent, but they cannot be sold or used for commercial purposes.

Explanatory Note
This Head outlines the process that must be followed when seeking consent for post-mortem activities.

Subhead 1 sets out the information which must be provided to a person being asked for consent. The information required is based on the recommendations of the Report of Dr Deirdre Madden on Post-Mortem Practice and Procedures (2006).

The consenting person must be given:

- sufficient information to understand what the post-mortem activities will entail;
- information on what types of tissue are likely to be removed;
- information on what information is available to them on request;
- information on the options available for burial, disposal, or return of tissue retained;
- information on the length of time tissue is likely to be retained; and
- the information that the post-mortem report will be made available to them on request.

The person must be made aware of the range of information available to them and they must be provided with this information on request before and/or after the procedure. Any information reasonably requested by the person giving consent must be provided to them, either before or after consent has been given. The Department will prepare guidelines on the information that must be provided.

Subhead 2 details the records which must be kept in respect of that consent. The written consent must be kept as part of the person's or mother's medical record (as appropriate) and kept on record in the hospital. A copy must be offered to the person who gave consent.

Subhead 3 provides for tissue samples to be taken from a person or fetus as part of the post-mortem procedures, and that these are to form part of the person's medical record, or in the case of a fetus, part of the mother's medical record.

Subhead 4 requires that accurate and detailed records of all tissue retained (except for tissue samples) must be kept in the hospital where the post-mortem takes place. Guidelines regarding the exact records that must be kept will be prepared by the Department.

Subhead 5 provides that a copy of the post-mortem report must be provided to the person who gave consent, upon their request.

Subhead 6 provides that tissue samples obtained during a post-mortem process that began before this Part comes into effect may still be used for post-mortem activities without further consent. However, they may not be sold or used for commercial purposes.

Head 30 Purposes for which a post-mortem examination may be taken

(1) A post-mortem examination may only be undertaken for one or more of the following purposes:

a. determining or providing further information on the cause of death;

b. providing information on the effectiveness of any medical or surgical intervention;

c. obtaining scientific or medical information which may be of benefit to another person now or in the future;

d. education and training;

e. research;

f. clinical audit and quality assurance; and/or

g. any other purpose which may be specified by the Minister in regulations.

Explanatory Note

This Head details the reasons for which a post-mortem examination may take place. These reasons are in line with the recommendations in the Report of Dr Deirdre Madden on Post-Mortem Practice and Procedures (2006).

A post-mortem examination may be undertaken to:

- determine, or provide further information on, the cause of death;
- provide information on the effectiveness of a medical or surgical intervention; and/or
- obtain scientific or medical information which may benefit another person now, or in the future.

A post-mortem procedure may also be undertaken for the purposes of education and training of medical personnel, for research, or for clinical audit and quality assurance.

The Minister may specify further purposes in regulations.

Head 31 Responsibility for carrying out post-mortem examination and compliance with provisions relating to them

(1) A post-mortem examination must be carried out under the supervision of a pathologist.

(2) A pathologist may authorise a person who is not a pathologist to carry out the removal of tissue from a deceased person or fetus provided the pathologist is satisfied that the person authorised is sufficiently qualified to perform the removal.

(3) Where tissue is supplied to third parties for the purpose of post-mortem activities, such arrangements must be clearly approved and documented by the CEO or owner of the hospital and in accordance with guidelines determined by the Minister.

(4) Hospitals in which post-mortem activities take place must name a responsible person. This named person will be responsible for compliance with the provisions of this Act and with any guidelines determined by the Minister. The hospital will ensure the responsible person is suitably qualified and in a position of authority to undertake this responsibility competently.

(5) The responsible person will ensure that an internal audit is regularly undertaken at each site where post-mortem activities are performed, to ensure that the hospital's policies and practices conform to the provisions of this Act and any guidelines determined by the Minister.

Explanatory Note

This Head defines the person responsible for carrying out post-mortem examinations and for ensuring compliance with the regulations set out in this Head.

Subhead 1 states that the person overseeing the post-mortem examination itself must be a registered pathologist.

Subhead 2 provides that a pathologist may authorize a qualified person to perform the removal of tissue as part of a post-mortem.

Subhead 3 provides that when supplying tissue to third parties for the purposes of consented post-mortem activities, these arrangements must be approved and documented by the CEO or owner of the hospital. This subhead allows the Minister to create guidelines in relation to this duty.

Subhead 4 requires a hospital which conducts post-mortems to name a legally responsible person who must ensure the hospital is complying with the provisions of this Act.

Subhead 5 provides that the responsible person is also responsible for ensuring that internal audits are regularly undertaken to the satisfaction of the regulator.

Head 32 Designation and functions of the regulator

(1) The Minister may designate, by regulation, a regulator for this Part of the Act.

(2) The regulator will monitor compliance with the provisions of this Part.

(3) The regulator:

a. may appoint one or more persons, as the regulator sees fit, to be authorised officers for the purposes of this Act; and

b. will furnish each authorised officer appointed by it with a warrant of the authorised officer's appointment.

(4) An authorised officer will, when performing a function imposed on an authorised officer under this Part of the Act, produce their warrant for inspection if requested to do so by a person affected by the performance of that function.

(5) The regulator will develop and put in place a system of monitoring and inspections for each site at which a post-mortem activity takes place for the purpose of ensuring that the site complies with the requirements of this Act, with regulations made under this Act, and with any standard guidelines determined by the Minister.

(6) The regulator may also serve a notice on the responsible person requiring that they furnish the regulator with such information concerning the hospital's compliance with this Act, or with regulations made under this Act, within the period of time which may be specified in the notice.

(7) Any person who receives a request for information in accordance with subhead (6) will provide the information requested within the period specified.

(8) Subject to subhead (9), a hospital shall notify the regulator, no later than one month before commencing post-mortem activities, of the proposed commencement, in such form and manner as may be prescribed by the regulator from time to time.

(9) A hospital which, on the commencement of these Regulations, is carrying out post mortem activities shall notify the Authority, no later than 3 months after the commencement of this Part, of such activity, in such form and manner as may be prescribed by the regulator, and may continue such activity pending said notification.

Explanatory Note

This Head allows for the Minister to appoint a regulator for this Part of the Act, and sets out the responsibilities and functions of the regulator.

Subheads 2-4 provide that the regulator will monitor compliance with the provisions of this Part, and provides for the regulator to appoint one or more authorised officers, who will be

furnished with a warrant. The authorised person must produce their warrant for inspection when performing duties and functions in accordance with their role.

Subhead 5 provides that the regulator will conduct inspections of sites where post-mortem activities are taking place, to ensure compliance with the requirements of this part.

Subheads 6 and 7 provide for the regulator to serve a notice on the legally appointed responsible person that compels them to provide the regulator with information concerning the hospital's compliance with this act and with regulations made under this act. A person who receives a request under must provide the information in the time specified.

Subheads 8 and 9 provide that hospitals which perform post-mortems, or intend to begin performing post-mortems, must notify the regulator.

It is proposed to expand the role of HIQA to take on the role of regulator for post-mortems under this Part.

PART 4 – Anatomical Examination

Head 33 Interpretation

(1) In this part, the following definitions apply:

"anatomical examination" means:

a. macroscopic or microscopic examination of a body for the purposes of teaching or studying, or training in or researching into, the structure of the human body by dissection; and

b. macroscopic or microscopic examination of a body for the purposes of teaching or studying, or training in or research into, surgical or clinical procedures by:
   i. removal of, or carrying out a procedure on or in relation to, one or more parts of the body;
   ii. implanting into the body any part of a body, prosthesis, or implant.

and where any part of the body is separated in the course of its anatomical examination the examination includes the examination of the part for those purposes.

"institution" means any place where anatomical examination takes place;

Explanatory Note

This Head defines key words and terms used in this Part.

Head 34 Consent to donate a body for anatomical examination

(1) An adult may give consent to donate their body or body parts for anatomical examination in writing, witnessed by another adult who must co-sign the written consent.

(2) Full and clear information should be provided to a person wishing to donate their body for anatomical examination. This information should include:

a. the nature of the activities for which the body will be used;

b. the length of time it, or its parts can be retained;

c. arrangements for disposal; and

d. any other information deemed appropriate by the Medical Council.

(3) The duration of time that the donor consents to their body being used for anatomical examination should be specified in the consent.

(4) Consent may be withdrawn or amended by the donor at any time before their death, in writing, to the licensed institution that their body had been offered.

(5) Consent is not required for the removal, storage and use of a deceased body or material from a deceased body for anatomical examination, if at least 100 years have elapsed since the date of the person's death.

(6) No financial or non-financial reward may be given in respect of the donation. No assistance may be given to the cost of private burial other than assistance with the provision of a coffin and transportation of the remains to the place of burial or cremation.

(7) Subhead (6) does not preclude the burial of the remains or cremated remains in a designated plot owned by or under the control of the institution to which the body was donated.

(8) Consent given for anatomical examination does not automatically confer consent for secondary activities, including research.

Explanatory Note
This Head sets out the conditions for consent to be given to donate one's body for use by an anatomy school for anatomical examination.

Subhead 1 provides that an adult may consent to donating a body or body parts for the purposes of anatomical examination. Consent must be given in writing, with a co-signing witness to the consent being present.

Subhead 2 provides for the information that must be provided to a person before giving consent to donate. Information on the nature of the activities to be performed, the length of time a body or body parts can be retained, and arrangements for disposal must be included. Any other information which may be required by the Medical Council must also be included.

Subhead 3 provides that the duration of time the donor consents to their body being used must be specified in the consent.

Subhead 4 provides that consent may be withdrawn at any time by the potential donor.

Subhead 5 provides that when a person has died over 100 years ago, there is no requirement to have consent to perform anatomical examination.

Subheads 6 & 7 provide that no financial or non-financial reward may be given in respect of the donation, except minor assistance with necessary expenses such as the supply of a plain coffin and transportation to the graveyard. The institution to which the body was donated may, in certain circumstances, provide a burial place if needed.

Subhead 8 provides that consent given for anatomical examination does not automatically confer consent for research or other secondary activities.

Head 35 Practice of anatomical examination

(1) Anatomical examination, for the activities described under part (a) of Head 33 may only be practised in an institution holding a licence issued by the Medical Council.

(2) Anatomical examination, for the activities described under part (b) of Head 33 may only be practised using a specimen loaned by or transferred from an institution holding a licence issued by the Medical Council or in an institution holding a license issued by the Medical Council.

(3) Only the responsible person(s) (see Head 39) named on the licence or a person authorised by or under the direction of the responsible person may undertake an anatomical examination.

(4) An institution holding a licence under the Anatomy Act 1832 on the coming into force of this Part of the Act may continue to carry out such activity provided that it submits an application for a licence to the Medical Council no later than 12 weeks after the coming into force of this Act and may continue to practice pending a decision by the Medical Council on the licence application.

(5) A body may be removed to a licenced institution and embalmed or otherwise preserved before the donor's death has been registered, but anatomical examination may not take place until it has been registered.

(6) The licensed institution is responsible for a donor's body and body parts from its acceptance for anatomical examination until the burial, cremation, disposal or return to the family.

(7) The Medical Council may develop, adopt, or approve guidelines on any matter which comes within the scope of this Part.

(8) All aspects of anatomical examination should be governed by documented, controlled and monitored policies and procedures and form part of the licensed institution's overall governance process.

Explanatory Note

This Head provides for the conditions under which anatomical examination can be carried out.

Subheads 1 & 2 provide that an anatomical examination, as defined in part (a) of Head 33 can only be conducted in an institution licenced by the Medical Council. An anatomical examination as defined in part (b) of Head 33 can only be carried out using a specimen sourced from a licensed institution, or in a licensed institution.

Subhead 3 provides that a responsible person (see Head 39) will be named on the license. Only the responsible person, a person authorised by the responsible person, or a person under their supervision may perform an anatomical examination.

Subhead 4 allows for institutions holding a license under the Anatomy Act 1832 (which will be repealed in this legislation) to apply for a new license under this legislation, and

allows them to continue to practice anatomy until the Medical Council makes a decision on their new license.

Subhead 5 provides that an anatomical examination can only be conducted on a body following the registration of the death. However, a body may be removed to an institution and preserved prior to registration.

Subhead 6 makes the licensed institution responsible for the donor's body or body parts from the time it is accepted by the institution until its burial or disposal.

Subhead 7 allows the Medical Council to develop guidelines for the practice of anatomy.

Subhead 8 requires that the licensed institution's governance process should involve documented, controlled, and monitored policies and procedures in all aspects of anatomical examination.

Head 36 Granting of a licence to perform anatomical examination

(1) The Medical Council may grant a licence to an institution to carry out anatomical examination, having satisfied itself that such anatomical examination shall be carried out by persons complying with the requirements of this Act.

(2) A license must name at least one responsible person (see Head 39) for the activities covered by the license. Only the responsible person(s) named on the license, a person authorised by the responsible person, or a person under the direction of the responsible person(s) may conduct an anatomical examination.

(3) An application for a licence shall:

a. be made in writing to the Medical Council;

b. include all relevant information as determined by the Medical Council;

c. include the name and qualifications of at least one responsible person; and

d. be accompanied by the appropriate fee.

(4) Where an institution applies for a license, the Medical Council may:

a. grant the license;

b. refuse to grant the license; or

c. grant the license subject to conditions.

(5) Where the Medical Council grants a license, it shall give notice in writing to the institution concerned specifying:

a. the particular site(s) at which anatomical examination may be carried out;

b. the responsible person; and

c. if the license is subject to conditions, the conditions which apply to the carrying out of anatomical examination.

(6) Where the Medical Council proposes to refuse to grant a licence, it shall serve a notice on the institution concerned of the proposed refusal and reasons for same, and shall, if any representations are made by or on behalf of the institution within 28 days after the date of such notice, consider the representations.

(7) Where the Medical Council, having considered the representations (if any) made by or on behalf of an institution in response to a notice under subhead (6) decides to refuse to grant a license, it shall notify the institution stating the reasons on which its decision is based.

Explanatory Note

This Head sets out the conditions under which the Medical Council can grant or refuse a licence to an institution to carry out anatomical examination.

Subhead 1 allows the Medical Council to grant a license if it is satisfied that the institution will conduct anatomical examination within the requirements of this Act.

Subhead 2 provides that a responsible person (or persons) must be named on the license, and that only the named person, persons under their supervision, or persons authorised by them can perform an anatomical examination.

Subhead 3 requires that the application be made in writing, in the form required by the Medical Council. The application must specify at least one responsible person. The application must also be accompanied by the appropriate fee.

Subheads 4-7 provide for the process by which the Medical Council can accept, reject, or accept subject to conditions, a license application. When the Council grants a license, it must give written notice to the institution, specifying the sites at which anatomical examination is permitted, and the persons responsible for overseeing anatomical examination. They must also specify any conditions which apply to the granting of the license. If the Council refuses an application, it must notify the institution and allow the institution to make representations within 28 days. After considering any representations, the Council must again write to the institution stating their decision and the reasons on which it is based.

Head 37 Removal, variation, and addition of conditions

(1) The Medical Council may at any time remove or vary a condition attaching to a license or impose an additional condition on a license.

(2) Where the Medical Council proposes to remove or vary a condition or impose an additional condition under subhead (1), it shall serve a notice on the licensed institution concerned which shall:

a. give details of the condition which it proposes to remove, vary, or impose;

b. give the reasons for this decision; and

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

Explanatory Note

This Head empowers the Medical Council to remove, add, or amend conditions relating to a license. This will allow the regulator to update conditions based on current best practice.

Subhead 2 provides that when the Medical Council intends to alter a condition under this head, it must notify the institution concerned in writing, advising of the change be made, the reasons for that change, and the date on which the change will occur.

Head 38 Suspension or revocation of a license

(1) The Medical Council may suspend or revoke a license on one or more of the following grounds:

a. that the licensed institution concerned is not in compliance with the requirements of this Part;

b. that anatomical examination cannot be carried out safely by the licensed institution;

c. that the information given by the licensed institution when applying for a license was false or incomplete in any material aspect;

d. that the licensed institution is not carrying out, or has indicated by a notice in writing that it no longer intends to carry out, the anatomical examination to which the license relates; or

e. the licensed institution does not have the staff, premises, equipment or facilities necessary for carrying out the anatomical examination to which the license relates.

(2) Where the Medical Council proposes to suspend or revoke a license, it shall serve a notice on the licensed institution concerned of the proposal and reasons for same, and shall, if any representations are made by the institution within 28 days after the date of such notice, consider those representations.

(3) Where the Medical Council, having considered any representations made by or on behalf of a licensed institution under subhead (2), decides to suspend or revoke a license, it shall notify the institution in writing stating the reasons on which the decision is based.

(4) Where the Medical Council considers it necessary in the interests of safety, it may, by a notice served on the licensed institution concerned, suspend or revoke a license immediately, or from a date specified in the notice.

(5) A suspension of a licence pursuant to this Part shall be for such a period and for such purposes as the Medical Council shall consider necessary having regard to the reasons for the suspension.

(6) Where, after a suspension has taken effect, the Medical Council considers that a license should be further suspended or revoked, the Medical Council shall proceed in accordance with the provisions of this Part.

(7) Where:

a. a licensed institution has failed, in any material respect, to comply with the requirements of this Part; or

b. the information given by a licensed institution when applying for a license was false or incomplete in any material respect,

and the Medical Council considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the license in the first instance, it may serve a compliance notice on the licensed institution in accordance with Head 66.

(8) Where the licensed institution fails to comply with the requirements set out in a compliance notice served under Head 66 within the specified timescale, the Medical Council may, by a further notice served on the licensed institution, suspend or revoke the license concerned.

Explanatory Note

This Head sets out the procedure the Medical Council must follow to suspend or revoke a license.

Subhead 1 provides for the grounds on which the Medical Council can suspend or revoke a license.

Subheads 2 & 3 provide that the Medical Council must notify the institution in writing of its decision to suspend or revoke a license, and consider any representations made by the institution within 28 days.

Subhead 4 provides that if the Council believe it to be in the interests of safety, they can immediately suspend or revoke a license.

Subheads 5 & 6 provide that the Medical Council shall suspend a license for any duration of time they consider necessary given the reasons for the suspension. If the Council believes it necessary, further suspension or revocation of a license may occur.

Subheads 7 & 8 provide for the Medical Council to issue compliance notices under Head 66 when an infraction does not warrant suspension or revocation. If the institution does not comply within the specified timescale, the Medical Council may proceed to suspend or revoke the license.

Head 39 Responsibilities of the responsible person(s)

(1) A licensed institution shall designate at least one appropriately qualified and experienced person as a "responsible person" qualified in accordance with subhead (3), whose services will be available to it. This person (or persons) shall be specified on the license.

(2) The responsible person shall ensure that:

a. anatomical examination is carried out in accordance with this Part;

b. information is provided to the Medical Council as required;

c. there is a system of documentation in place (see Head 43).

(3) The responsible person must have:

a. a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of:
   i. a university course of study; or
   ii. a course recognised as an equivalent course by the Medical Council; and

b. practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under this Part for at least 2 years, in an institution licenced to practice anatomical examination.

(4) A licenced institution shall inform the Medical Council of the name and qualifications of any additional responsible persons designated under subhead (1) after the grant of the licence concerned.

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

(6) The responsible person should have a system of documentation in place to ensure appropriate training, delegation of responsibility and accountability for these persons.

(7) If the Medical Council considers that a responsible person (or persons) does not meet the requirements of subhead (3), it shall serve a notice to that effect on the licensed institution concerned.

(8) If, within a period of 14 days of receiving the notice under subhead (7), a licensed institution is not able to demonstrate to the reasonable satisfaction of the Medical Council that the responsible person meets the requirements of subhead (3), it shall:

a. relieve the individual of the duties of the responsible person in respect of the licensed institution;

b. appoint a new responsible person (or persons) in their place; and

c. notify the Medical Council that it has appointed a new responsible person or persons and provide details of the name and qualification of the person(s) appointed.

(9) The responsible person must make annual returns to the Medical Council in a manner prescribed by the Medical Council.

(10) Where the responsible person(s) are permanently or temporarily replaced, the licensed institution shall provide immediately the name of the new responsible person(s), their qualifications, and their date of commencement, to the Medical Council for approval.

Explanatory Note

This Head sets out the responsibilities of the responsible person or persons named on the license and provisions in relation to anatomical examination.

Subheads 1-4 provide that each licensed institution must name at least one responsible person, who must be named on the license. The named person will be responsible for ensuring that the regulations under this Part are followed, that information is provided to the Medical Council as appropriate, and that an appropriate system of documentation is in place.

The named person must be suitably qualified, having evidence of a relevant formal qualification and appropriate postgraduate experience working in the area of anatomical examination. Any additional responsible person must be made known to the Medical Council.

Subheads 5 and 6 allow the responsible person to delegate their responsibilities to individuals with appropriate training to perform those duties. A system of documentation is required to record the qualifications, training, and duties of these persons.

Subheads 7 and 8 provide for the Medical Council to serve a notice on the institution if they believe a responsible person is not suitably qualified. If a notice is served, the institution has 14 days in which to satisfy the Medical Council that the qualification requirements are met. If the Medical Council is not satisfied at the end of this period, the institution must then relieve the current responsible person of their duties, appoint a new responsible person in their place, and inform the Medical Council of the new appointment.

Subhead 9 provides that the responsible person must make annual returns to the Medical Council in the manner prescribed by the Council.

Subhead 10 provides that when a responsible person is replaced temporarily or permanently, the licensed institution must immediately provide the name and qualifications of the new responsible person to the Medical Council for approval.

Head 40 Importation of specimens for anatomical examination

(1) The importation of specimens for anatomical examination may only be undertaken with the authorisation of the Medical Council.

(2) Imported specimens should be obtained, transported, used and disposed of by licensed institutions in accordance with the consent given by the donor.

(3) Where the specimens are imported into the country for the purposes of anatomical examination, evidence of compliance with the legal requirements in the country of origin of those specimens, which should be of a similar standard to those in effect in Ireland, will also be required.

(4) License holders must be able to demonstrate to the Medical Council that the requisite consent is in place.

(5) Imported specimens must have:

a. documentary evidence of the origin of specimens;

b. evidence of the appropriate consent from the donor for the proposed use;

c. relevant details, as may be determined by guidelines drawn up by the Medical Council, regarding the donor or donors; and

d. evidence of compliance with the legal requirements of the country of origin of the specimens.

Explanatory Note

This Head provides for the importation of specimens for anatomical examination.

Subheads 1-3 provide that importation of specimens for anatomical examination must be done only with the authorisation of the Medical Council. Any specimens imported for use in anatomical examination must be obtained, transported, used, and disposed of in accordance with the consent given by the donor. When specimens are to be imported, the license holder must provide evidence that they have complied with the laws of the country from which the specimens originated. These laws should be of a similar standard to the equivalent Irish laws.

Subheads 4 and 5 provide that license holders who wish to import specimens must provide documentary evidence of the provenance of specimens, evidence of appropriate consent, evidence of compliance with the legal requirements of the country of origin, and any other relevant details that may be required.

Head 41 Exportation of specimens for anatomical examination.

(1) The exportation of specimens for anatomical examination may only be undertaken with the authorisation of the Medical Council.

(2) Specimens for exportation should be obtained, used, transported, and stored in accordance with the consent given by the donor.

(3) Donors should be provided with adequate information to indicate that their donated specimens may be exported. The donor, or a donor's designated family member, as appropriate, should be provided with information to indicate whether or not the remains will be repatriated and within what timeframe.

(4) Specimens for exportation must have:

a. documentary evidence of the origin of specimens;

b. evidence of consent from the donor for the proposed use, including evidence of specific consent for its exportation to another country; and

c. details of where and when the body is going to be cremated, buried, or disposed of.

Explanatory Note

This Head provides for the exportation of specimens for anatomical examination.

Subheads 1-2 provide that exportation of specimens for anatomical examination can be done only with the authorisation of the Medical Council. Any specimens exported for use in anatomical examination must be obtained, transported, used, and disposed of according to the consent given by the donor.

Subhead 3 provides that donors should be provided with adequate information to indicate that their donated specimens may be exported. This information should indicate if and when remains will be repatriated. Information regarding repatriation should also be made available to the donor's next-of-kin, as appropriate.

Subhead 4 provides that license holders who wish to export specimens must provide documentary evidence of the provenance of specimens, evidence of appropriate consent, and details of where and when the body will be cremated, buried, or disposed of.

Head 42 Loan/Transfer of Anatomical Specimens

(1) The loan or transfer of specimens for the purposes described under Head 33(a) should only be between licensed institutions and should be kept on licensed premises only.

(2) The loan or transfer of specimens for the purposes described under Head 33(b) may be between licensed institutions or from a licensed institution to a health professional.

(3) A loan should be for a defined period and subject to a written, signed agreement between the parties. The agreement should indicate the specimens covered by it, where the specimens will be held, and the purpose and timespan of the loan.

(4) While the specimen is on loan, it will remain the responsibility of the lending party, except where noted in Subhead (7).

(5) When a specimen is transferred to a health professional under subhead (2), the licensed institution's responsible person must ensure that:

a. the recipient is an appropriately qualified health professional;

b. the premises where the anatomical examination will take place and where the specimen will be stored are fit for purpose;

c. that the recipient of the loan treats the specimen with dignity and respect.

(6) The loaned specimen's records (see Head 43) should be transferred with the specimens to the receiving institution or health professional and the lending institution should retain copies of all records.

(7) The receiving institution or health professional receiving the transfer will be responsible for the return of the specimens to the lending party, or disposal of the specimens in line with the provision of consent.

Explanatory Note
This Head provides for the requirements for the loan and transfer of anatomical specimens.

Subhead 1 provides that loans/transfers of specimens for use for the purpose of Head 33(a) (teaching/studying/training/research into the structure of the body) may only be entered into between licensed institutions.

Subhead 2 provides that loans/transfers of specimens for use for the purpose of Head 33(b) (teaching/studying/training/research into the surgical/clinical procedures) may only be entered into between two licensed institutions, or a lending licensed institution and receiving health professional.

Subheads 3-4 provides that a loan should be subject to a written agreement between the parties and be for a specified amount of time. The lending party remains responsible for the specimen, except for the return or disposal of specimens (see subhead 7).

Subhead 5 provides that when a loan is to a health professional under subhead (2), the responsible person at the lending institution must ensure that the receiving party is appropriately qualified, that the premises on which the examination is to take place and where the specimen is to be stored are fit for purpose, and that the recipient of the loan treats the specimen with dignity and respect.

Subhead 6 provides that all records pertaining to the donation should be transferred with the specimen, and the lending institution should retain copies of those documents.

Subhead 7 provides that the receiving institution is responsible for the return of the specimens to the lending party, or for disposal of the specimens in line with the consent given, as appropriate.

Head 43 Records to be kept in relation to donated anatomical specimens.

(1) A copy of the Medical Certificate of the Cause of Death and the death registration should be kept at the institution receiving the donation.

(2) A copy of the donor's written consent should be kept at the licensed institution receiving the donation.

(3) The responsible person should have a system of documentation in place to record the relevant training undertaken and the responsibilities delegated to individuals under this Part.

(4) There should be a systematic record management system that ensures data protection and confidentiality, and with suitable provision for data back-up. There should be a documented internal audit system, with an appropriate schedule and accountability. Staff should be appropriately qualified and trained for their work.

(5) All licensed institutions should keep records in a secure and permanent form for each anatomical specimen in their possession.

(6) These records should be held on the premises that the anatomical specimen was first received and on any other premises to which the anatomical specimen has been transferred.

(7) Records should be kept after disposal of the anatomical specimen and permanently maintained in line with a documented records management policy.

(8) All records must be available for inspection and review by the Medical Council.

Explanatory Note
This Head sets out the records that must be kept by licensed institutions in relation to donated anatomical specimens and the manner in which they must be kept.

Subheads 1 & 2 state that the death registration, the Medical Certificate of Cause of Death, and the written consent to donate must be kept at the receiving institution.

Subheads 3-8 requires that the responsible person puts in place a system of documentation to record the training undertaken and responsibilities delegated to other people, and to set up record management system that protects the privacy of the donors and that has appropriate backups to protect against data loss. Records must be kept securely and permanently at the receiving institution and any other institution that holds a specimen. The Medical Council must have access to all records for inspection and review purposes.

Head 44 Appointment of an Inspector of Anatomy

1. The Medical Council will appoint an appropriately qualified and experienced person to the post of Inspector of Anatomy.

2. A person appointed as Inspector of Anatomy will be subject to the terms and conditions determined by the Medical Council with the prior approval of the Minister given with the consent of the Minister for Public Expenditure and Reform.

3. A person holding the post of Inspector of Anatomy will be paid by the Medical Council, out of the funds at its disposal, the remuneration and allowances determined under subhead (2).

4. The Inspector will:

    a. be responsible for monitoring compliance with this Part of the Act, any conditions which may be associated with the license, and any guidelines adopted, approved, or developed by the Medical Council in respect of anatomical examination;

    b. conduct inspections not less than once every three years of all places where anatomical examination is performed;

    c. issue recommendations to the responsible person in respect of any improvements in respect of the standards of practice which may be required or any other issues arising from such inspections;

    d. report to the Medical Council on the results of their inspections;

    e. advise the Medical Council, on their own initiative or at the Council's request, on any matter related to anatomical examination;

    f. make an annual report to the Medical Council not later than 30 June of the following year on their activities;

    g. at the request of the Medical Council and as soon as it is practicable after they receive the request, provide the Medical Council with such information as the Medical Council specifies in its request; and

    h. perform other such functions as the Medical Council may determine.

5. Subject to the requirements of the Act, the Medical Council may determine the procedures and protocols to be followed by the Inspector.

6. The Medical Council may appoint one or more persons as they see fit to be authorised officers to assist the Inspector of Anatomy for the purposes of this Part of the Act.

7. The Medical Council shall provide the person or persons appointed under subheads (1) and (6) with warrants:

a. identifying the person or persons; and

b. specifying the functions that the person, or persons, have the authority to perform by virtue of this Head.

8. Where a person or persons appointed under subhead (1) or (6) performs a function specified in that person's warrant provided under subhead (7), that person or persons shall produce the warrant for inspection at the request of a person in respect of whom the function is performed.

Explanatory Note

This Head provides for the Medical Council to appoint a person, or persons, to be Inspector(s) of Anatomy.

Subheads 1-3 provide that the Medical Council may appoint an Inspector of Anatomy under terms and conditions set out by the Minister approved by the Department of Public Expenditure and Reform. The Inspector will be paid by the Medical Council.

Subhead 4 outlines the duties of the Inspector of Anatomy. The Inspector will be responsible for ensuring compliance with this Part of the Act, and with any associated guidelines. The Inspector will conduct inspections as necessary, report to the Medical Council on inspections, advise the Medical Council on matters relating to anatomy. The Inspector will be required to make an annual report to the Medical Council, and provide any information requested by the Council in respect of their duties as Inspector.

Subhead 5 provides that the Medical Council may determine the procedures and protocols followed by the Inspector.

Subheads 6-8 provide that the Inspector may appoint a person or persons as authorised officers to assist in their duties, and that the Medical Council will provide these authorised persons with warrants, which must be produced when requested during an inspection.

Head 45 Existing anatomical holdings

(1) This Act does not apply to bodies or body parts donated under the Anatomy Act 1832 or imported for anatomical examination on or before the date on which this Act comes into effect.

Explanatory Note

This Head provides that the regulations under this Part do not apply to specimens donated prior to this Act coming into effect.

Head 46 Repeals and Amendments

(1) The 1832 Anatomy Act will be repealed on a date which the Minister will specify by order.

(2) Section 106 of the Medical Practitioners Act 2007 will be repealed on a date which the Minister will specify by order.

(3) Section 4(3)(a) of the Assisted Decision-Making (Capacity) Act 2015 will be repealed on a date which the Minister will specify by order.

Explanatory Note

This Head provides for the repeal of:

- the 1832 Anatomy Act;
- Section 106 of the Medical Practitioner's Act 2007; and
- Section 4(3)a of the Assisted Decision-Making (Capacity) Act 2015.

Section 22(2) of S.I. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012) provides that "Organs shall not be procured in the case of a deceased donor unless consent to the donation has been given by the deceased donor's next of kin." Section 22(2) of the S.I. may need to be amended to take account of deemed consent.

PART 5 – Public Display

Head 47 Interpretation

(1) In this Part, "tissue" does not include a human fetus or gamete.

(2) In this Part, the following definitions apply:

"Public Display" means an exhibition, show or display in which a body or part of a body of a deceased person is used for the purpose of being exposed to view by the public in venues other than:

a. sites specified on a licence issued pursuant to Head 36;

b. places in the State, being places where training is provided to persons undertaking training for a basic medical qualification, which are subject to inspection under Head 88(2)(f) of the Medical Practitioners Act 2007;

c. sites operated by the National Museum of Ireland;

"Specimen" means a body, body part, or tissue sample held by a licensed institution and donated in accordance with the consent required under this Part;

Explanatory Note

Subhead 1 excludes a human fetus or gamete from the definition of tissue in this Part.

Subhead 2 defines other key words and terms used in this Part.

Head 48 Public display activities

(1) Subject to the exceptions in subhead (2), "public display activities", in this Part, means:

a. the use of the body, body parts, and tissue of a deceased person for the purposes of public display;

b. the removal, retention, storage and transport of a body, body parts, and tissue for the purposes of public display;

c. the disposal of a body, body parts, and tissue once its use for the purpose of public display is concluded.

(2) The Medical Council may make decisions as to what constitutes public display for the purposes of this part.

(3) "Public display activities", in this part, do not include the following:

a. display of a body, body parts, or tissue for the purposes of a funeral; or any other ceremony in which final respects are paid to the deceased; or which is incidental to the ceremony;

b. display of a body, body parts, or tissue at a place of public religious worship, where the body, body part, or tissue is essential to the act of religious worship;

c. display of the body, body part, or tissue in print, photographic, or internet material;

d. the filming of medical procedures for the purposes of teaching or research.

(4) Public display activities can only be undertaken by a person holding a licence granted by the Medical Council under Head 50.

Explanatory Note

Subheads 1-3 define "public display activities". "Public display activities" includes the use of bodies, body parts, and tissues for the explicit purpose of public display, but also includes the removal, retention, storage, transport, and disposal of tissue being used for this purpose. This Head also allows the regulator (the Medical Council) to make decisions as to other activities that may be defined as public display. The definition of public display excludes funerals and similar ceremonies, religious worship where the human tissue is central to the act of worship, display via photograph or online, and filming for the purposes of training or teaching.

Subhead 4 provides that public display activities may only be undertaken by a person who holds a license granted under Head 50 by the Medical Council.

Head 49 Consent to donate a body, body parts, or tissue for public display activities

(1) An adult may give consent to donate their body, body parts, or tissue for public display activities to an institution licensed under Head 34. This consent must be given in writing, witnessed by another adult who must co-sign the written consent.

(2) Full and clear information should be provided to a person wishing to donate their tissue for public display activities. This information should include:

a. the nature of the activities for which the body, body parts, or tissue can be used;

b. the length of time it, or its parts can be retained;

c. arrangements for disposal;

d. any other information deemed appropriate by the Medical Council.

(3) The duration of time that the donor consents to their body being used for public display activities should be specified in the consent.

(4) Consent may be withdrawn or amended by the donor at any time before their death, in writing, to the license holder that their donation had been offered.

(5) No financial or non-financial reward may be given in respect of the donation. No assistance may be given to the cost of private burial other than assistance with the provision of a coffin and transportation of the remains to the place of burial or cremation.

(6) Consent given for public display activities does not automatically confer consent for secondary activities, including research.

Explanatory Note
This Head sets out the conditions for consent to be given to donate one's body, body parts, or tissue for use in public display.

Subhead 1 provides that an adult may consent to the donation of a body, body parts, or tissue for the purposes of public display. Consent must be given in writing, with a co-signing witness to the consent being present.

Subhead 2 provides for the information that must be provided to a person before giving consent to donate. Information on the nature of the activities to be performed, the length of time a body or body parts can be retained, and arrangements for disposal must be included. The Medical Council may require further information to be included.

Subhead 3 provides that the duration of time the donor consents to their body being used must be specified in the consent.

Subhead 4 provides that consent may be withdrawn at any time by the potential donor.

Subhead 5 provides that no financial or non-financial reward may be given in respect of the donation, except minor assistance with necessary expenses such as the supply of a plain coffin and transportation to the graveyard.

Subhead 6 provides that consent given for public display activities does not automatically confer consent for research or other secondary activities.

Head 50 Granting of a licence to use specimens for public display activities

(1) The Medical Council may grant a licence to an individual to carry out public display activities, having satisfied itself that such activities shall be carried out by persons complying with the requirements of this Act.

(2) An application for a licence shall:

a. be made in writing to the Medical Council;

b. include all relevant information as determined by the Medical Council;

c. include copies of the written consent of each person whose body, body parts, or tissue will be used for public display activities;

d. include the particular site where public display activities will be carried out; and

e. be accompanied by the appropriate fee.

(3) Where a person applies for a license, the Medical Council may-

a. grant the license;

b. refuse to grant the license; or

c. grant the license subject to conditions.

(4) Where the Medical Council grants a license, it shall give notice in writing to the person concerned specifying-

a. the person licensed to carry out public display activities;

b. details of the particular site at which public display activities may be carried out; and

c. if the license is subject to conditions, the conditions which apply to the carrying out of public display activities.

(5) Where the Medical Council proposes to refuse to grant a licence, it shall serve a notice on the person concerned of the proposed refusal and reasons for same, and shall, if any representations are made by or on behalf of the person within 28 days after the date of such notice, consider these representations.

(6) Where the Medical Council, having considered the representations (if any) made by or on behalf of a person in response to a notice under subhead (5) decides to refuse to grant a license, it shall notify the person stating the reasons on which its decision is based.

Explanatory Note

This Head sets out the conditions under which the Medical Council can grant or refuse a licence to an institution to undertake public display using human tissue.

Subhead 1 allows the Medical Council to grant a license if it is satisfied that the person to be licensed will conduct public display within the requirements of this Act.

Subhead 2 requires that the application be made in writing, in the form required by the Medical Council, and specifying the site at which public display will be conducted. The application must also be accompanied by the appropriate fee.

Subheads 3-6 provide for the process by which the Medical Council can accept, accept subject to conditions, or reject a license application. When the Council grants a license, it must give written notice to the institution, specifying the sites at which public display activities are permitted. They must also specify any conditions which apply to the granting of the license. If the Council refuses an application, it must notify the institution and allow the institution to make representations within 28 days. After considering any representations, the Council must again write to the institution stating their decision and the reasons on which it is based.

Head 51 Conditions for holding a license for Public Display

(1) Specimens used for public display activities must be treated with appropriate dignity and respect.

(2) License holders may not display a specimen while:

a. any procedure in relation to an anatomical examination;

b. any similar procedure, including any dissection, is being carried out; or

c. the body or a part of the body is such that the deceased person can be recognised simply by examination of the body or body part.

(3) The Medical Council may at any time remove or vary a condition attaching to a license or impose an additional condition on a license.

(4) Where the Medical Council proposes to remove or vary a condition or impose an additional condition under subhead (3), it shall serve a notice on the license holder concerned which shall:

a. give details of the condition which it proposes to remove, vary, or impose;

b. give the reasons for this decision; and

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

Explanatory Note

This Head sets out the basic conditions that apply for holding a license on Public Display.

Subheads 1 & 2 provide that specimens are treated with respect and dignity, and that license holders are barred from displaying specimens during anatomical procedures or similar dissections. License holders are also barred from publicly displaying a specimen that can be recognised or identified by visual examination of the body or body part.

Subheads 3 & 4 empower the Medical Council to remove, add, or change conditions regarding the granting of the license. This will allow the regulator to update conditions based on current best practice. When the Medical Council intends to alter a condition under this head, it must notify the person concerned in writing at least 14 days in advance.

Head 52 Suspension or revocation of license

(1) The Medical Council may suspend or revoke a license on one or more of the following grounds:

a. that the license holder concerned is not in compliance with the requirements of this part;

b. that public display activities cannot be carried out safely by the license holder;

c. that the information given by the license holder when applying for a license was false or incomplete in any material aspect;

d. that the license holder is not carrying out, or has indicated by a notice in writing that it no longer intends to carry out, the public display activities to which the license relates; or

e. if the facilities at the site specified in the license are not fit for purpose.

(2) Where the Medical Council proposes to suspend or revoke a license, it shall serve a notice on the license holder concerned of the proposal and reasons for same, and shall, if any representations are made by the license holder within 28 days after the date of such notice, consider those representations.

(3) Where the Medical Council, having considered any representations made by or on behalf of a license holder under subhead (2), decides to suspend or revoke a license, it shall notify the license holder in writing stating the reasons on which the decision is based.

(4) Where the Medical Council considers it necessary in the interests of safety, it may, by a notice served on the license holder concerned, suspend or revoke a license immediately, or from a date specified in the notice.

(5) A suspension of a licence pursuant to this Part shall be for such a period and for such purposes as the Medical Council shall consider necessary having regard to the reasons for the suspension.

(6) Where, after a suspension has taken effect, the Medical Council considers that a license should be further suspended or revoked, the Medical Council shall proceed in accordance with the provisions of this Part.

(7) Where:

a. a license holder has failed, in any material respect, to comply with the requirements of this Part; or

b. the information given by a license holder when applying for a license was false or incomplete in any material respect, and the Medical Council considers that the failure in question is not sufficiently serious to warrant suspension or

revocation of the license in the first instance,

the Medical Council may serve a compliance notice on the license holder in accordance with Head 66.

(8) Where the license holder fails to comply with the requirements set out in a compliance notice served under subhead (7) within the specified timescale, the Medical Council may, by a further notice served on the license holder, suspend or revoke the license concerned.

Explanatory Note
This Head sets out the procedure the Medical Council must follow to suspend or revoke a license.

Subhead 1 provides for the grounds on which the Medical Council can suspend or revoke a license.

Subheads 2 & 3 provide that the Medical Council must notify the institution in writing of its decision to suspend or revoke a license, and consider any representations made by the institution within 28 days.

Subhead 4 provides that if the Council believe it to be in the interests of safety, they can immediately suspend or revoke a license.

Subheads 5 & 6 provide that the Medical Council shall suspend a license for any duration of time they consider necessary given the reasons for the suspension. If the Council believes it necessary, further suspension or revocation of a license may occur.

Subheads 7 & 8 provide for the Medical Council to issue compliance notices when an infraction does not warrant suspension or revocation. A compliance notice must identify the requirements that the institution has failed to comply with and the actions necessary to correct the issue, and the timeframe in which the institution must comply. If the institution does not comply within the specified timescale, the Medical Council may proceed to suspend or revoke the license.

Head 53 Importation of specimens for public display activities

(1) The import of specimens for public display activities may only be undertaken with the authorisation of the Medical Council.

(2) Imported specimens should be obtained, transported, used and disposed of by license holders in accordance with the consent given by the donor.

(3) Where the specimens are imported into the country for the purposes of public display, evidence of compliance with the legal requirements in the country of origin of those specimens, which should be of a similar standard to those in effect in Ireland, will also be required.

(4) License holders must be able to demonstrate to the Medical Council that the requisite consent is in place.

(5) Imported specimens must have:

a. documentary evidence of the origin of specimens;

b. evidence of the appropriate consent from the donor for the proposed use;

c. evidence of compliance with the legal requirements of the country of origin of the specimens.

d. relevant details, as may be determined by guidelines drawn up the Medical Council, regarding the donor or donors.

Explanatory Note

This Head provides for the importation of specimens for public display.

Subheads 1-3 provide that importation of specimens for public display must be done only with the authorisation of the Medical Council. Any specimens imported for use in public display must be obtained, transported, used, and disposed of in accordance with the consent given by the donor. When specimens are to be imported, the license holder must provide evidence that they have complied with the laws of the country from which the specimens originated, and that these laws are of a similar standard to those in Ireland.

Subheads 4-5 provide that license holders who wish to import specimens must provide documentary evidence of the provenance of specimens, evidence of appropriate consent, evidence of compliance with the legal requirements of the country of origin, and any other details that may be required by the Medical Council regarding the donors.

Head 54 Exportation of specimens for public display activities.

(1) The exportation of specimens for public display activities may only be undertaken with the authorisation of the Medical Council.

(2) Specimens for exportation should be obtained, used, transported, and stored in accordance with the consent given by the donor.

(3) Donors should be provided with adequate information to indicate that their donated specimens may be exported. The donor should be provided with information to indicate whether or not the remains will be repatriated and within what timeframe.

(4) Specimens for exportation must have:

a. documentary evidence of the origin of specimens;

b. evidence of consent from the donor for the proposed use, including evidence of specific consent for its exportation to another country; and

c. details of where and when the body is going to be cremated, buried, or disposed of.

Explanatory Note
This Head provides for the exportation of specimens for public display.

Subheads 1-2 provide that exportation of specimens for public display can be done only with the authorisation of the Medical Council. Any specimens exported for use in public display must be obtained, transported, used, and disposed of in accordance with the consent given by the donor.

Subhead 3 provides that donors should be provided with adequate information to indicate that their donated specimens may be exported. This information should indicate if and when remains will be repatriated.

Subhead 4 provides that license holders who wish to export specimens must provide documentary evidence of the provenance of specimens, evidence of appropriate consent, and details of where and when the body will be cremated, buried, or disposed of.

Head 55 Records to be kept in relation to specimens donated for public display activities

(1) A copy of the Medical Certificate of the Cause of Death and the death registration should be kept by the license holder.

(2) A copy of the written consent that pertains to each specimen should be kept by the license holder.

(3) The license holder should keep records in a secure and permanent form for each specimen in their possession.

(4) All records must be available for inspection and review by the Medical Council.

Explanatory Note

This Head sets out the records that must be kept by licensed institutions in relation to donated specimens and the manner in which they must be kept.

Subheads 1 & 2 state that the Medical Certificate of the Cause of Death, the death registration, and the written consent to donate must be kept by the license holder.

Subhead 3 provides that records should be kept by the license holder for each specimen in their possession, and that these records should be kept permanently and securely.

Subhead 4 provides that records must be made available for inspection and review by the Medical Council.

Head 56 Existing specimens

(1) The requirements under this Part do not apply to bodies, body parts, or tissues where the donor died one hundred years before the commencement of this Act.

(2) The requirements under this Part do not apply to bodies, body parts, or tissues on public display in Ireland at the time this Act is commenced.

Explanatory Note
This Head provides that the regulations under this Part do not apply to specimens over 100yrs old at the time this Act is commenced.

Subhead 2 provides that this Part does not apply to specimens on display at the time this Act is commenced.

Head 57 Designation and functions of the regulator

(1) The regulator will monitor compliance with the provisions of this Part.

(2) The regulator may approve, adopt, or develop guidelines on any matter which comes within the scope of this part.

(3) The regulator:

a. may appoint one or more persons, as the regulator sees fit, to be authorised officers for the purposes of this Act; and

b. will furnish each authorised officer appointed by it with a warrant of the authorised officer's appointment.

(4) An authorised officer will, when performing a function imposed on an authorised officer under this Part of the Act, produce their warrant for inspection if requested to do so by a person affected by the performance of that function.

(5) The regulator will develop and put in place a system of monitoring and inspections for each site specified on a license for public display for the purpose of ensuring that the site complies with the requirements of this Act, with regulations made under this Act, and with any standard guidelines determined by the regulator.

(6) The regulator may also serve a notice on a license holder requiring that they furnish the regulator with such information concerning the license holder's compliance with this Act, or with regulations made under this Act, within the period of time which may be specified in the notice.

(7) Any person who receives a request for information in accordance with subhead (6) will provide the information requested within the period specified.

Explanatory Note

Subhead 1 allows the Minister to appoint a regulator for this Part of the Act.

Subheads 2-5 provide that the regulator will monitor compliance with the provisions of this Part, and provides for the regulator to appoint one or more authorised officers, who will be furnished with a warrant. The authorised person must produce their warrant for inspection when performing duties and functions in accordance with their role.

Subheads 6 and 7 provide for the regulator to serve a notice on a responsible person that compels them to provide the regulator with information concerning the transplant centre's compliance with this act and with regulations made under this act. A person who receives a request under must provide the information in the time specified.

It is proposed that the Medical Council will assume the role of regulator under this Part.

PART 6 – Offences and Penalties

Head 58 Offences

(1) It shall be an offence for a person not to comply with the requirements set out in this Act and in regulations made under this Act.

Explanatory Note
This Head provides that it shall be an offence not to comply with the requirements outlined in this Act and in regulations made under this Act.

Head 59 Offences by Corporate Bodies

(1) Where an offence under this Act is committed by a body corporate and is proved that the offence was committed with the consent or connivance, or was attributable to any wilful neglect of any person who was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in that capacity, that person, as well as the body corporate, shall be guilty of an offence and may be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, subhead (1) applies 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.

Explanatory Note

This Head provides for an offence by a body corporate or company. If an offence is committed by a body corporate or a company with the consent, knowledge, or wilful neglect of an officer of the body corporate, then both that person and the body corporate will be guilt of an offence.

Subhead 2 provides that if a body corporate is managed by its members, subhead (1) applies to the acts of a member acting in that capacity as it they were a director or manager.

Head 60 Penalties

(1) A person who contravenes a provision under this Act shall be liable:

a. on a first summary conviction to a class B fine or higher, or imprisonment for a term not exceeding 1 year or both;

b. on any subsequent summary conviction to class A fine or higher, or imprisonment for a term not exceeding 5 years or both; or

c. on conviction on indictment to a fine or imprisonment for a term not exceeding 20 years or both.

(2) Unless it is satisfied that there are special and substantial reasons for not so doing, the court shall, where the person is convicted of an offence, order a person to pay to the prosecution the costs and expenses, measured by the court, incurred by the prosecution in relation to the investigation, detection or prosecution of the offence.

(3) The costs and expenses referred to in subhead (2) are exclusive of any other fine or penalty set by the Court.

Explanatory Note

Subhead 1 sets out the penalties and fines for a first offence and subsequent offences under the Act.

It is proposed that the penalties will be fines ranging from €1000 - €100,000 and jail terms ranging from 1 – 20 yrs.

Subhead 2 obliges the Court to order any person convicted under the Act to pay the regulator the costs and expenses incurred by the regulator in relation to the investigation and the prosecution of the offence, unless there are particular reasons for not doing so.

Subhead 3 provides that any expenses and costs to be paid under subhead (2) are in addition to any fine or penalty set by the Court. This subhead is modelled on section 80 of the Consumer Protection Act 2007.

Head 61 Proceedings

(1) Summary proceedings for an offence under this Act may be brought and prosecuted by the regulator.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for any offence under this Act may be commenced at any time within the 12 months from the date on which the offence was committed.

Explanatory Notes
This Head is modelled on section 18 of the Public Health (Standardised Packaging of Tobacco) Act 2014 and section 22 of the Public Health (Sunbeds) Act 2014. This Head provides for the regulator to bring and prosecute summary offences under this act, at any time within one year from the date on which the offence was committed.

Head 62 Defence of Due Diligence

(1) In proceedings for an offence under this Act, or regulations made under this Act, it shall be a defence for the person against whom proceedings are brought to show that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(2) Where a person is charged with an offence under this Act it is a defence for the person to show that at the time of the activity, the person reasonably believed that the activity was carried out in accordance with the requirements of the Act.

Explanatory Note
This Head is a standard provision. Its purpose is to allow a person who is in breach of the Act to claim in his or her defence that he or she took all reasonable precautions to avoid the breach or reasonably believed that the activity was authorised.

Head 63 Powers of Inspection, Search and Entry

(1) For the purposes of enforcing compliance with this Act or conducting inspections under Heads 24, 32, 44, or 57 an authorised officer may:

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

(i) any premises at which any activity governed by Parts 2, 3, 4, 5 or 6 are carried out;
(ii) any premises at which books, records or other documents (including documents stored in non-legible form) relating to any such activities are stored or kept,

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

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

d. carry out, or have carried out, such tests, examinations, analyses, inspections and checks of:

(i) the premises,

(ii) any relevant thing at the premises, or

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

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

e. require any person at the premises or the owner or person in charge of the premises and any person employed there to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as he or she may reasonably require for the purposes of his or her functions under this Act,

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

g. direct that relevant thing found at the premises not be moved from the premises, without his or her consent,

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

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

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

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

(2) When performing a function under this Act, an authorised officer may, subject to any warrant under subhead (4), be accompanied by such number of:

a. other authorised officers;

b. members of the Garda Síochána; or

c. persons with expertise relating to any relevant matter,

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

(3) An authorised officer will not enter a dwelling, other than:

a. with the consent of the occupier; or

b. in accordance with a warrant issued under subhead (4).

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

a. a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling;

b. books, records or other documents (including documents stored in non-legible form) referred to in subhead (1)(a)(ii) are being stored or kept in any dwelling; or

c. a dwelling is occupied in whole or in part by an undertaking carrying out any licensable activity,

may issue a warrant authorising a named authorised officer accompanied by such other authorised officers, members of the Garda Síochána, or persons with expertise relating to any relevant thing, as may be necessary, at any time or times, within one month of the

date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under subhead (1)(b) to (k).

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

(6) A statement or admission made by a person on foot of a requirement under subhead (1)(e) shall not be admissible as evidence in proceedings brought against that person for an offence, other than an offence under subhead 9(a).

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

(8) A person who falsely represents himself or herself as an authorised officer commits an offence.

(9) A person who:

a. obstructs or impedes an authorised officer, an Inspector of Anatomy, or a member of the Garda Síochána in the exercise a power under this Head;

b. without reasonable excuse, does not comply with a request or requirement of an authorised officer under this Head; or

c. in purported compliance with such a requirement gives information that is false or misleading in a material respect,

commits an offence.

(10) A person who fails to comply with a request under subhead 5 or, gives information that is false or misleading in a material respect, commits an offence and is liable on summary conviction to a Class A fine.

(11) Where an authorised officer is of the opinion that there is non-compliance with a requirement of a Part this Act, the authorised person may, following consultation with the Chief Executive Officer of the regulator for that Part or another officer of the regulator designated for that purpose, serve, or arrange to have served, on the undertaking or other person concerned a notice ("compliance notice") in accordance with paragraph (12).

(12) A compliance notice shall:

a. be signed by the authorised person issuing it, or the officer consulted in accordance with paragraph (11);

b. identify the requirement(s) of this Act with which there has not been compliance.

c. for the purpose of ensuring compliance by the person concerned, require the person to do or refrain from doing such act or acts as is or are specified in the notice by such date as is so specified, and

d. contain information regarding the bringing of an appeal under paragraph (15) against the notice, including the manner in which an appeal shall be brought.

(13) A compliance notice shall not specify a date in accordance with paragraph (2)(c) that falls on or before the date by which an appeal under paragraph (5) shall be brought.

(14) An authorised person may, following consultation with the Chief Executive Officer of the regulator or another officer of the regulator designated for that purpose—

a. withdraw a compliance notice at any time, as he or she considers appropriate; or

b. where no appeal is brought under this Regulation, specify a date extending the period specified in the notice for the purposes of paragraph (12)(c), and notify the person in writing accordingly.

(15) A person may appeal a compliance notice served on the person to the District Court not later than 14 days after the service of the compliance notice concerned.

(16) A person who appeals against a compliance notice shall at the same time notify the Authority of the appeal and the grounds for the appeal and the Authority shall be entitled to appear, be heard and adduce evidence at the hearing of the appeal.

(17) The District Court shall, upon an appeal under this Regulation, do one of the following:

a. affirm the compliance notice concerned; or

b. direct the authorised person to withdraw the compliance notice concerned.

(18) An authorised person shall comply with a direction under paragraph (17).

(19) A person who fails to comply with a compliance notice by the specified date is guilty of an offence.

(20) This Regulation shall not operate to prevent or restrict:

a. the entitlement of any person to bring proceedings for the purpose of securing compliance with these Regulations by a person, or

b. the bringing or prosecuting of any proceedings for an offence under these Regulations.

(21) In this Regulation “specified date” means, in relation to a compliance notice:

a. the date specified in the notice in accordance with paragraph (2)(*c*), where no appeal against the notice is brought under this Regulation, or

b. the day falling immediately after the expiration of the period of seven days from the date on which the District Court so affirms the notice, where an appeal against the notice is brought under paragraph (5) and the District Court affirms the notice in accordance with paragraph (7)(*a*)

Explanatory Note
This Head sets out the regulator's powers of entry, search and seizure and provides for the issuing of compliance notices.