



**An Bille um Fhíochán Daonna (Trasphlandú,
Scrúdú Iarbháis, Scrúdú Anatamaíoch agus Taispeáint
Phoiblí), 2022**

**The Human Tissue (Transplantation, Post-Mortem,
Anatomical Examination and Public Display) Bill 2022**

Meabhrán Míniúcháin
Explanatory Memorandum



**AN BILLE UM FHÍOCHÁN DAONNA (TRASPHLANDÚ,
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**THE HUMAN TISSUE (TRANSPLANTATION, POST-MORTEM,
ANATOMICAL EXAMINATION AND PUBLIC DISPLAY)
BILL 2022**

EXPLANATORY MEMORANDUM

Introduction

The Human Tissue Bill is a composite piece of legislation that includes provisions on

- Organ donation and transplantation
- Post-mortem practices and procedures
- Anatomical examination
- Public display of bodies after death

The introduction of the legislation will bring Ireland into line with international practice in relation to governance of practices relating to human tissue. It is the international norm to have primary legislation governing organ donation and transplantation, and the Bill introduces Ireland's first legislative framework in this area.

Purpose

The purpose of the Bill is to embed in legislation the idea that consent is the defining principle across all practices relating to human tissue and to introduce necessary safeguards and regulation across these areas.

The Bill is intended to support and increase organ donation and transplantation in Ireland. It will introduce a soft opt-out system of consent, where consent for organ donation is deemed unless the person has, while alive, registered his/her wish not to become an organ donor after death. The Bill will also broaden the donor pool through the introduction of frameworks for living donation, including for non-directed altruistic donation.

Separately, the Bill also addresses many of the concerns raised in the Report of Dr Deirdre Madden on Post-Mortem Practice and Procedures (2005) by introducing a statutory requirement for consent for non-coronial post-mortems and by providing for regulation of post-mortems in hospital settings.

The Bill repeals the Anatomy Act of 1832 and replaces it with legislative arrangements governing the donation of bodies to anatomy schools and standards to be met in the practice of anatomy.

Finally, the Bill includes provisions for the governance of the public display of bodies in Ireland.

Provisions of the Bill

The Bill is divided into six Parts. Further details of the provisions included in each of these parts follows.

PART 1

Preliminary and General Matters

Section 1 – Short title, commencement and collective citation

Section 1 provides for citation of the Bill when enacted as the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination, and Public Display) Act 2022. It further provides for commencement of the Act or commencement of its various sections, as the Minister so orders including those to be commenced following consultation with the Minister for Justice. The section also provides for joint citation with the Coroners Acts where appropriate.

Section 2 – Interpretation

Section 2 is a standard provision that sets out definitions of terms used throughout the Bill to assist with interpretation of the legislation.

Section 3 – Regulations

Section 3 is a standard provision that enables the Minister to make regulations for certain matters referred to in the Bill and for the laying of regulations before the Houses of the Oireachtas.

Section 4 – Expenses

Section 4 is a standard provision that deals with expenses that may arise in the administration of the legislation.

Section 5 – Service of documents

Section 5 sets out the standard provisions for the service of documents and describes how a notice or other document may be served to a named person under this Bill.

Section 6 – Guidelines

Section 6 enables the Minister to issue guidelines for the purpose of providing guidance to clinicians and others regarding the operation of, and compliance with, this Bill.

Section 7 – Designated family member in relation to relevant person

Section 7 defines the term “designated family member” and outlines its use in the Bill. The designated family member is someone who has an established relationship with the deceased. They will be consulted regarding consent or confirmation of no objection for organ and tissue and cell donation or non-coronial post-mortem examination as appropriate within the provisions of the Bill.

The section sets out who will be considered a “designated family member” for the purposes of this Bill and sets out exceptions to these provisions. It allows for consent/confirmation of no objection to be obtained from the family member who has been the main point of contact for clinicians in their treatment of the deceased. In instances where such a scenario does not apply, the designated family member will be determined via a hierarchy set out in subsection 2.

The section further requires that when making their decision, the designated family member must give substantial weight to whether the deceased would have had an objection to the transplantation, removal or post-mortem examination in question.

Section 8 – Provisions for storage, handling, transportation, and respectful disposal or return of bodies, anatomical specimens, organs or tissue

Section 8 sets out conditions for the storage, handling, transportation, disposal and return of organs, tissue, bodies, body parts and anatomical specimens in accordance with the Bill. It legislates that such activity should have due regard to the dignity, bodily integrity and privacy of the deceased person and mandates that written records be kept in respect of these activities to ensure traceability.

PART 2

Transplantation

Chapter 1

Preliminary and general

Section 9 – Interpretation and application

Section 9 is a standard provision and provides for additional definitions to help with interpretation of this Part of the Bill. It further clarifies the type of human material that falls under the remit of the transplantation provisions in the Bill and which do not.

Section 10 – Deemed consent and appropriate consent – general provisions

Section 10 outlines what “deemed consent” and “appropriate consent” mean in respect of this Part of the Bill. The concept of “deemed consent” is strictly for the purposes of this Part and applies specifically to donation of specific organs by a deceased adult where the individual has not registered an objection to becoming an organ donor on the Organ Donation Opt-Out Register. This section also defines “appropriate consent” for the purposes of this Part and describes the scenarios where appropriate consent should be sought.

The process for recording consent or no objection in the case of deemed consent is also set out in this section of the Bill.

Section 11 – Transplantation activities

Section 11 defines the term “transplantation activities” and outlines the conditions under which transplantation activities may take place. Carrying out transplantation activities outside of these conditions is an offence under the Bill.

Section 12 – Principles governing organ and tissue and cell donation

Section 12 outlines the principles of organ and tissue and cell donation. These include that donation must be voluntary and unpaid, and it makes it an offence to seek or offer financial or non-financial rewards by advertising the need for or availability of organs or tissues and cells.

The section does however allow for a living donor to receive expenses for loss of income and costs connected to the donation and sets out the conditions for this. The Minister for Health is given the authority to make regulations in respect of compensation under this section.

Section 13 – Priority of organ donation

Section 13 provides that consent to organ donation for transplantation will have priority over consent for any other purpose, including post-mortem examination (Part 3), donation for anatomical examination (Part 4), or public display (Part 5). This section is subject to the Coroners Acts

1962 to 2020 and does not apply if the body comes under the jurisdiction of the coroner.

Section 14 – Removal of tissue sample to determine viability of transplantation

Section 14 provides that a clinician may remove a tissue sample from a proposed donor to determine the viability of transplantation if it is considered necessary or expedient and in circumstances where consent for donation has been secured.

Section 15 – Preservation for transplantation activities – deceased persons

Section 15 provides for clinicians to take steps to preserve organs or tissues and cells that may be suitable for transplantation while consent or confirmation of no objection to donation is being sought. This provision ceases to apply if it is established that a designated family member objects to the donation.

Section 16 – Certification for transplantation activities – deceased donor

Section 16 sets out the specific steps which must be followed ahead of transplantation activities taking place in instances involving a deceased donor. These include ensuring that the relevant consent or confirmation of no objection is in place and that the Coroner has signed off on organ or tissue and cell retrieval in instances of death that fall under the jurisdiction of the Coroner's Acts. Failure to comply with either of these two measures is an offence under the Bill.

Chapter 2

Consent

Section 17 – Deemed consent for donation of relevant organs and removal of relevant organs

Section 17 sets out the conditions where deemed consent applies and the process to be followed by clinicians in instances of deemed consent. It also lists exemptions for deemed consent. This section further stipulates that the wishes of the deceased must be considered by the designated family member when deciding whether to object to organ donation.

This section also identifies the point up to which consent can be amended or withdrawn.

Section 18 – Consent for organ donation given by designated family member where deemed consent does not apply

Section 18 provides conditions for organ donation where deemed consent does not apply and where consent must be sought from a designated family member. It prohibits clinicians from removing an organ from a deceased person unless they are satisfied that consent is in place.

Section 19 – Consent for tissue and cells donation given by designated family member in respect of deceased adult donor

Section 19 provides for the donation of tissue and cells from deceased donors and the conditions for obtaining consent to such donation.

Section 20 – Consent by parent or guardian in respect of deceased child

Section 20 outlines the conditions which must be met and the steps that must be followed for organ and tissue and cell donation in respect of a deceased child under the age of 18.

Chapter 3

Conditions in relation to donation

Section 21 – Conditions in relation to donation of organs by living adults

Section 21 sets out the conditions which must be met for the donation of organs by living adult donors, including the information that must be provided and the principles that must be adhered to for such donation. It also identifies the point up to which consent can be amended or withdrawn.

Section 22 – Conditions in relation to donation of tissues and cells by living adults

Section 22 sets out the conditions which must be met for the donation of tissues and cells by living adult donors including the information that must be provided and the principles that must be adhered to for such donation. It also identifies the point up to which consent can be amended or withdrawn.

Section 23 – Conditions in relation to donation of organs by non-directed altruistic donors

Section 23 sets out the conditions that must be met before a person can donate an organ to a person who is not known to them (also known as “altruistic donation”). Altruistic donors donate to the transplant pool rather than directing their donation to a specific person. The section provides for the information that must be provided to donors and the principles that must be adhered to for such donation. Approval for such donation must be given by the independent panel established under Section 26.

Section 24 – Conditions in relation to donation of organs and tissues and cells by living adults who lack capacity

Section 24 sets out the conditions that must be met and steps that must be followed before the donation of tissues and cells by living adults who lack capacity can take place. It prohibits living organ donation by adults who lack capacity, unless that organ must be removed as part of a domino transplant operation. It also sets out the process for obtaining consent in such a scenario. The donation of tissues and cells by living adults who lack capacity must be approved by the independent panel established under Section 26.

Section 25 – Conditions in relation to donation of organs and tissues and cells by living children

Section 25 sets out the conditions that must be met and steps that must be followed before the donation of tissues and cells by living children. It also prohibits living organ donation by children unless that organ must be removed as part of a domino transplant operation. Consent for living donation by a child of tissues and cells must be sought from a parent/guardian of the child and approval for the donation must be given by the independent panel established under Section 26.

Chapter 4

Independent panel

Section 26 – Independent panel for certain cases of living donation of organs and tissue and cells

Section 26 provides for the Minister for Health to establish an independent panel to authorise living donation of organs and tissues in certain scenarios which require additional safeguards to protect the potential donor.

Section 27 – Composition of Panel

Section 27 sets out the composition of the panel which will consist of 8 members. This section also stipulates specific competencies for certain panel members.

Section 28 – Application to Panel for non-directed altruistic donation

Section 28 provides for the process by which an application is made to the panel for approval for non-directed altruistic donation and the steps that the panel must take when considering such an application.

Section 29 – Application to Panel for donation of regenerative tissue by living adults who lack capacity

Section 29 provides for the process by which an application is made to the panel for approval for donation of tissue and cells by adults who lack capacity. It stipulates the conditions under which such a donation can take place and outlines the steps that the panel must take when considering such an application.

Section 30 – Application to panel for donation of regenerative tissue by living child

Section 30 provides for the process by which an application is made to the panel for approval for donation of tissue and cells by living children. It stipulates the conditions under which such a donation can take place and outlines the steps that the panel must take when considering such an application.

Chapter 5

Relevant Organ Donation Opt-out Register

Section 31 – Relevant Organ Donation Opt-Out Register

Section 31 provides that an Organ Donation Opt-Out Register be established and maintained by the Health Service Executive (HSE). All adults have the option to register their objection to becoming an organ donor after death i.e., to “opt-out” of organ donation. The register will be securely maintained and will not be accessible to the public.

Section 32 – Application to register objection to being relevant organ donor

Section 32 outlines the process to be followed by an individual who wishes to be included on the Organ Donation Opt-Out Register. It details the information that an applicant shall provide as part of his or her registration. The section also allows for an individual to amend or withdraw their registration and prohibits individuals from registering or amending the details of others on the Register without prior consent from the person concerned.

Section 33 – Application to ascertain if objection registered on Register

Section 33 stipulates that a clinician shall apply to the HSE to seek confirmation of whether a person is listed on the Register in cases where donation is being considered. It also details the steps that should be taken once they have received such information.

Chapter 6

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

Section 34 – Authority to monitor compliance with Part 2

Section 34 gives the Health Products Regulatory Authority (HPRA) the necessary powers to serve as regulator of Part 2 of the Bill. Any functions relating to the Panel (established under Section 26) or the Opt-Out Register (established under Section 31) are excluded from this provision.

Section 35 – Consequential amendments to Regulations of 2006

Section 35 provides for amendments to the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006) that are necessary to support the functioning of Part 2 of the Bill.

Section 36 – Consequential amendments to Regulations of 2012

Section 36 provides for amendments to the European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012) that are necessary to support the functioning of Part 2 of the Bill.

PART 3

Pathology Practice

Chapter 1

Preliminary and General

Section 37 – Definitions (Part 3)

Section 37 is a standard provision and provides for additional definitions to help with interpretation of this Part of the Bill.

Section 38 – Application of Part

Section 38 sets out that the provisions in this Part of the Bill shall only apply to post-mortem activities that take place in a hospital setting.

The section also clarifies that the provisions of this Part do not apply to post-mortem activities initiated before the commencement of this section. Post-mortems directed by the Coroner are exempt from the legislation subject to the amendments made to the Coroners Acts under Sections 56 and 57 of the Bill.

Section 39 – Regulations for purposes of Part, including regulations to apply to certain aspects of coronial post-mortems that take place in hospitals

Section 39 empowers the Minister for Health to make regulations to support the management and the respectful and appropriate conduct of post-mortem examinations. Among other things, the regulations may provide for managing the conduct of post-mortem examinations, with specific emphasis on the retention, storage and disposal of body parts, organs and tissues.

This section also identifies a number of persons that the Minister will consult with as appropriate before making regulations, including the Minister for Justice and a number of other named stakeholders.

It is also stipulated that nothing in Sections 38 or 39 or in regulations made thereunder will prevent a coroner or any other person from complying with his or her obligations under the Coroners Act 1962 to 2020.

Chapter 2

Consent and post-mortem activities

Section 40 – Consent – general provisions

Section 40 sets out the process for obtaining consent for the conduct of post-mortem activities that do not fall under the jurisdiction of the Coroner, including non-coronial post-mortem examinations. It details the information that must be provided to the person giving consent, stipulates requirements around record keeping in respect of consent and provides for consent to be limited to certain activities.

Section 41 – Post-mortem activities

Section 41 defines what constitutes “post-mortem activities” for the purposes of this Part and makes it an offence to carry out such activity without the appropriate consent.

Section 42 – Removal and retention of organs and other body parts during non-coronial post-mortem examination

Section 42 sets out conditions applying to non-coronial post-mortem examinations. It includes provisions relating to maintenance of records and the conduct of the examinations while also prohibiting payment for organs or tissues removed during a non-coronial post-mortem examination. The section further reinforces the necessity for appropriate consent for the removal of any organ or tissue while clarifying that consent need only be given once in respect of any particular post-mortem activity.

The section also allows for any tissue sample removed prior to commencement to be retained for purposes associated with the post-mortem examination without appropriate consent although it prohibits the sale or use of such samples for commercial purposes unless there is appropriate consent.

Section 43 – Purposes for which post-mortem activities may be undertaken

Section 43 lists the purposes for which post-mortem activities may be undertaken.

Section 44 – Carrying out of non-coronial post-mortem examination

Section 44 identifies the medical professionals who can conduct a non-coronial post-mortem examination and allows for technical assistance to be provided to enable such an examination. For the purpose of this Bill, post-mortems can be undertaken by a pathologist or a registered medical practitioner under the supervision of a pathologist.

Section 45 – Report of post-mortem examination

Section 45 requires that a report must be prepared following a non-coronial post-mortem examination and sets out what information shall be recorded in that report and how the report should be retained.

Section 46 – Consent for post-mortem activities on adult

Section 46 sets out the conditions in relation to consent for post-mortem activities on a deceased adult. Consent may be given by the adult prior to their death or it can be given by a designated family member.

Section 47 – Consent for post-mortem activities on deceased child

Section 47 sets out the conditions in relation to consent for post-mortem activities on a deceased child. Consent must be given by a parent or guardian of the child. If one parent or guardian should object, any consent that may previously have been given by the other parent or guardian is nullified.

Section 48 – Consent for post-mortem examination of foetus

Section 48 sets out the conditions in relation to consent for post-mortem activities on a foetus. It stipulates that consent must be given by the mother of the foetus or a person acting on her behalf.

Section 49 – Commercial purposes and consent for use

Section 49 sets out the conditions under which material derived from non-coronial post-mortems can be used by a third party (such as pharmaceutical companies) for commercial purposes. The section stipulates that such use must first be authorised by the person in charge of the hospital and that consent must then be sought from the appropriate person as identified in sections 46-48 (designated family member; parent or guardian; or mother).

The section clarifies that consent need only be given once in respect of any particular post-mortem activity and stipulates that agreements with any third party will be recorded and approved in writing by the person in charge of the hospital.

Section 50 – Application by Minister to High Court

Section 50 empowers the Minister for Health to make an application to the High Court to allow a non-coronial post-mortem examination to be undertaken where consent has not been given. Such an application should only be made in exceptional circumstances, namely where it is required in the interests of public health or where there is a risk to public health if the post-mortem is not conducted.

Section 51 – Nominated person

Section 51 requires that each hospital that conducts post-mortem activities must appoint a nominated person who will serve as the main contact point for the regulator as well as fulfilling other responsibilities as set out.

The section delineates the responsibilities of such “a nominated person” for the purposes of this Part.

Section 52 – Authority to monitor compliance with Part 3 – authorised persons etc

Section 52 grants the Health Information and Quality Authority (HIQA) the power to regulate this Part. Specifically, it provides that an authorised person appointed under section 70 of the Health Act of 2007 shall be an authorised person under this Part and makes necessary amendments to the 2007 Act to support and enable HIQA’s role in this regard.

Section 53 – Compliance notices

Section 53 sets out the circumstances whereby an authorised person may issue a compliance notice under this Part and sets out the steps which such a person must follow in relation to the notice. The section also sets out the obligations that must be followed by the person on whom a compliance notice has been served.

Section 54 – Appeal of compliance notice

Section 54 sets out the appeal procedures that are available to a person on whom a compliance notice has been served.

Section 55 – Prohibition orders

Section 55 gives HIQA the power to serve prohibition orders for egregious breaches of the provisions of this Part of the Bill. The section also sets out the procedures which must be followed in relation to issue of the order and details the appeals procedures available to the person on whom the order has been served.

Chapter 3

Amendments to Act of 1962

Section 56 – Amendment of section 33 of Act of 1962

Section 56 will amend the existing provisions in the Coroners Act to ensure that the family of a deceased person, subject to a coronial post-mortem examination is informed that material removed during the examination may be retained for the purposes of the death investigation and is informed of the location of the hospital or other facility.

The section also stipulates that where the post-mortem examination has been conducted in a hospital, any material removed from the body shall be preserved, stored and recorded by the registered medical practitioner in accordance with regulations made in that regard by the Minister for Health or by the Minister for Justice in respect of another facility.

Section 57 – Amendment of Act of 1962

Section 57 will introduce two new sections to the Coroners Act to formalise the final interactions between a coroner and a designated person in a hospital or other facility where coronial post-mortems on the deceased person occur.

New section 33F (Authorisation for disposition) will ensure that family members are made aware, as soon as practicable by the coroner, that any material retained following the post-mortem examination is no longer required. This notification will advise the family member to contact the nominated person to arrange for the authorisation for the final disposition of the material. The section also authorises a coroner to direct disposal of material considered historic, which may have been stored for a long period and whose retention serves no further purpose.

A further new section 33G (Regulations in respect of conduct of post-mortems in places other than hospitals, etc.) will enable the Minister for Justice to make such regulations for the purpose of proper management and conduct of post-mortem examinations that are made in places other than hospitals.

PART 4

Anatomical Examination

Section 58 – Definitions (Part 4)

Section 58 is a standard provision and provides for additional definitions to help with interpretation of this Part of the Bill.

Section 59 – Application of Part

Section 59 provides that this Part of the Bill will only apply to anatomical examinations that occur after the commencement of the section and exempts examinations that have begun under the provisions of the Anatomy Act 1832.

Section 60 – Consent to donate body for anatomical examination

Section 60 sets out the conditions for obtaining consent from an individual who wishes to donate their body for anatomical examination and provides for the Medical Council, as regulator, to specify particular requirements around consent. The section also prohibits payment or other inducements for such consent and makes it an offence to conduct an anatomical examination without consent.

Section 61 – Medical certificate of cause of death must be signed before anatomical examination can take place

Section 61 allows for a body to be transferred to a licensed institution before a death is registered but stipulates that a Medical Certificate of Cause of Death must be signed before an anatomical examination can take place. The Medical Certificate of Cause of Death must be retained by the licensed institution which received the body.

Section 62 – Practice of anatomical examination

Section 62 prescribes who is authorised to perform an anatomical examination and prohibits the performance of such examinations in locations other than licensed institutions. It also confers responsibility for the donor's body or parts of the body to the licensed institution from time of receipt until burial, cremation or return.

Section 63 – Loan or transfer of anatomical specimens for purposes of anatomical examination

Section 63 sets out the conditions under which the loan or transfer of anatomical specimens is permitted for the purposes of anatomical examination. Loan or transfer is only permitted between institutions on the island of Ireland and is subject to pre-authorisation from the Medical Council, as regulator for this Part.

Both the institution which lends or transfers the specimen and the institution which receives the loan or transfer must be able to provide the Medical Council, if requested, with evidence the loan or transfer was made with any consent given by the donor and in accordance with the provisions of this Part.

Section 64 – Importation of anatomical specimens for anatomical examination

Section 64 sets out the conditions under which anatomical specimens can be imported for anatomical examination. Importation is subject to pre-authorisation from the Medical Council and an anatomical specimen must be obtained, transported, used, and disposed of in accordance with any consent given by the donor.

Section 65 – Licensed institutions

Section 65 sets out the process to be followed by an institution that wishes to apply for a licence to perform anatomical examinations. It includes a grandfathering clause for institutions already licensed under the Anatomy Act 1832.

Section 66 – Notification of grant of licence to institution

Section 66 outlines the process to be followed by the Medical Council when issuing a licence for anatomical examination following a successful application from an institution.

Section 67 – Material amendment of licence

Section 67 sets out the process by which a licensed institution can apply to have its licence amended.

Section 68 – Removal, variation or addition of conditions

Section 68 empowers the Medical Council to remove, add, or amend conditions relating to a licence issued under Section 65 and outlines the process to be followed for doing same.

Section 69 – Suspension and revocation of licences

Section 69 sets out the procedure that the Medical Council must follow if it intends to suspend or revoke a licence and details the conditions under which it can take such action.

Section 70 – Medical Council may suspend a licence without notice in certain circumstances

Section 70 sets out the conditions under which the Medical Council can suspend a licence without notice and details the procedure to be followed when taking such action. It also makes provision for any licensed institution aggrieved by such notice to make an application to the High Court.

Section 71 – Appeal from decision (other than decision under section 70) of Medical Council

Section 71 sets out the procedures for a licensed institution that wishes to appeal a decision by the Medical Council in circumstances other than when a licence has been suspended without notice.

Section 72 – Responsible persons

Section 72 requires that a licensed institution must identify a responsible person who will serve as the main contact point for the regulator as well as fulfilling other responsibilities as set out in the legislation.

The section delineates the responsibilities of the responsible person for the purposes of this Part and allows for appropriate delegation of their functions.

Section 73 – Records to be kept in relation to donated anatomical specimens

Section 73 sets out the records that a responsible person must keep and maintain in respect of anatomical specimens donated for the purposes of anatomical examination. The section also includes provisions in relation to record keeping where a specimen is loaned, transferred or disposed of.

Section 74 – Transfer of functions from inspectors of places in State where anatomy is carried on under and in accordance with Anatomy Act 1832 to Medical Council

Section 74 provides for the transfer of functions from an Inspector of Anatomy granted powers under the Anatomy Act of 1832 to the Medical Council. The section outlines specific functions to be undertaken by the Medical Council and provides that the Medical Council shall have all the powers necessary or expedient to perform its functions under this Part.

Section 75 – Requests by Medical Council for information

Section 75 empowers the Medical Council to request any information it deems necessary from a licensed or applicant institution in order to fulfil its functions under this Part. It further stipulates that such requests must be complied with by the relevant institution.

Section 76 – Authorised officers for purposes of Part 4

Section 76 empowers the Medical Council to appoint authorised officers for the purpose of regulation under this Part.

Section 77 – Powers of authorised officers (Part 4)

Section 77 sets out the powers of authorised officers appointed under Section 76. The section also details the requirements of those being inspected and makes it an offence to obstruct or not comply with an authorised officer.

Section 78 – Codes of practice (anatomical examination)

Section 78 sets out the process by which the Medical Council can prepare, publish, amend or revoke a code of practice for anatomical examinations or approve any other code of practice relating to the undertaking of anatomical examinations as it deems necessary.

The section also provides for consent to the publication or approval, as the case may be, of such codes of practice by the Minister for Health.

Section 79 – Compliance notices (anatomical examination)

Section 79 sets out the circumstances whereby the Medical Council may issue a compliance notice under this Part and sets out the steps the Council must follow when doing so. It further provides that the person on whom the compliance notice has been served may make representations to the Medical Council about the proposed notice.

If a person in receipt of a compliance notice fails to comply with that notice, they will be guilty of an offence.

Section 80 – Appeal of compliance notice

Section 80 sets out how a person in receipt of a compliance notice may appeal such a notice and details the process of appeal.

PART 5

Public Display Activities

Section 81 – Definitions (Part 5)

Section 81 is a standard provision and provides for additional definitions to help with interpretation of this Part of the Bill.

Section 82 – Public display activities

Section 82 delineates what is encompassed by the term “public display activities” and sets out specified activities that do not constitute public display for the purposes of the Bill. The section also prohibits the use of the body of a child, human foetus, embryo or gamete for purposes of public display.

Section 83 – Licence required for public display activities

Section 83 states that a public display activity cannot take place unless a licence has been issued by the Medical Council in accordance with this Part. The section describes conditions that must be followed by licence holders in this regard and makes it an offence to be in breach of these obligations.

Exemptions to the requirement for a licence are also provided in the section.

Section 84 – Consent to donation of body etc. for public display activities

Section 84 sets out the conditions for obtaining consent from an individual who wishes to donate their body for public display and provides for the Medical Council, as regulator, to specify particular requirements around consent. The section also prohibits payment or other inducements

for such consent and makes it an offence to engage to display a body in public without a licence or without consent.

Section 85 – Medical certificate of cause of death must be signed before public display activities can take place

Section 85 allows for a body to be transferred to a Part 5 licence holder before a death is registered but stipulates that a Medical Certificate of Cause of Death must be signed before public display can take place. The Medical Certificate of Cause of Death must be retained at the premises of the Part 5 licence holder that received the body.

Section 86 – Application for Part 5 licence to undertake public display activities

Section 86 sets out the process for applying for a licence to undertake public display activities and the requirements of both the applicant and the Medical Council in this regard. It also sets out conditions for importing anatomical specimens into Ireland for public display.

The section also includes details of the appeals proposal available to the applicant should the Medical Council refuse a request for a licence.

Section 87 – Placing of conditions upon licence

Section 87 empowers the Medical Council to remove, add, or vary conditions relating to a licence and the process to be followed for doing same.

Section 88 – Suspension and revocation of Part 5 licences

Section 88 sets out the steps the Medical Council must follow if it intends to suspend or revoke a licence and conditions under which it can do so. The section also includes details of the appeals process available to the Part 5 licence holder in the event the Medical Council should seek to suspend or revoke a licence.

Section 89 – Suspension of licence without notice in certain circumstances

Section 89 sets out the conditions under which the Medical Council can suspend a licence without notice and the process to be followed when taking such action. Such a suspension should only be considered when there is a danger to life, health, or welfare of the public or an anatomical specimen is not being treated with dignity or respect. The section also makes provision for the Part 5 licence holder aggrieved by such a decision to make an application to the High Court.

Section 90 – Appeal from decision (other than decision under section 89) of Medical Council

Section 90 sets out the procedures for a Part 5 licence holder that wishes to appeal a decision by the Medical Council in circumstance other than when a licence has been suspended without notice under Section 89.

Section 91 – Loan or transfer of anatomical specimens for purposes of public display activities

Section 91 sets out the conditions under which the loan or transfer of anatomical specimens for the purposes of public display can take place. Loan or transfer is only permitted between licence holders on the island of Ireland and is subject to pre-authorisation from the Medical Council, as regulator for this Part.

Section 92 – Importation of anatomical specimens for purposes of public display activities

Section 92 sets out the conditions under which anatomical specimens can be imported for public display activities. Importation is subject to pre-authorization from the Medical Council and the Part 5 licence holder must satisfy himself or herself that any anatomical specimen has been obtained, transported, used, and disposed of in accordance with any consent given by the donor.

Section 93 – Records to be kept in relation to anatomical specimens

Section 93 imposes a requirement on the Part 5 licence holder to keep a register of documents pertaining to anatomical specimens donated for public display. The section details the documents required in the case of anatomical specimens imported for public display activities and the documents required where other circumstances apply. Failure to maintain a document register is treated as an offence.

Section 94 – Medical Council to monitor compliance with provisions of Part 5

Section 94 empowers the Medical Council to act as regulator for this Part and sets out the responsibilities of the Medical Council in its performance of this function.

Section 95 – Authorised officers for purposes of Part 5

Section 95 empowers the Medical Council to appoint authorised officers for the purpose of regulation under this Part.

Section 96 – Powers of authorised officers – Part 5

Section 96 sets out the powers of authorised officers appointed under Section 95. The section also details the requirements of those being inspected and makes it an offence to obstruct or not comply with an authorised officer.

Section 97 – Codes of practice (public display)

Section 97 sets out the process by which the Medical Council can prepare, publish, amend or revoke a code of practice for public display or approve any other code of practice relating to the undertaking of public display as it deems necessary.

The section also provides for consent to the publication or approval, as the case may be, of such codes of practice by the Minister for Health.

Section 98 – Compliance notices (public display)

Section 98 sets out the circumstances whereby the Medical Council may issue a compliance notice under this Part and sets out the steps the Council must follow when doing so. It further provides that the person on whom the compliance notice is to be served may make representations to the Medical Council about the proposed notice.

If a person in receipt of a compliance notice fails to comply with that notice, they will be guilty of an offence.

Section 99 – Appeal of compliance notice

Section 99 sets out how a person in receipt of a compliance notice may appeal such a notice and details the process of appeal.

PART 6

Miscellaneous

100. – Amendment of Act of 2007

Section 100 lays out the amendments needed to the Health Act of 2007 to support the Medical Council's role as regulator of Parts 4 and 5 of the Bill.

101. – Repeals

Section 101 provides for the necessary repeals to existing legislation to support the functioning of the Bill. Section 106 of the Health Act of 2007 and the Anatomy Act 1832 are both repealed.

102. – Offences and penalties

Section 102 outlines the penalties for offences under the Act where not stated in the main body of the Bill. The section includes standard provisions for when offences under the Bill are committed by a body corporate.

103. – Defences

Section 103 outlines what shall be considered a defence for someone who is accused of an offence under this Bill when proceedings are taken against them.

104. – Sharing of information in certain circumstances

Section 104 facilitates information sharing between the regulators of the various parts of the Bill.

105. – Data protection

Section 105 designates data controllers for each of the Parts of the Bill and outlines how data is to be processed and maintained subject to existing GDPR legislation

An Roinn Sláinte,

Nollaig, 2022.