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Bill Digest

Human Tissue Bill

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Abstract

The *Human Tissue (Transplantation, Post-mortem, Anatomical Examination and Public Display) Bill 2022* seeks to provide a legal framework for the treatment of and consent for the following separate, designated activities:

(i) organ and tissue donation and transplantation;

(ii) hospital post-mortem (i.e. a post-mortem other than a coroner's post-mortem);

(iii) anatomy;

(iv) public display of bodies.

The Bill provides for an *opt-out* system of consent for deceased organ donation and an associated register; it formalises practice and procedure (e.g. introduces regulations where codes of practice currently apply); and it allows for the dignified disposal/return of by-products of these activities.

Tithe an Oireachtais
Houses of the Oireachtas

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Legal Disclaimer

Summary

This Bill is a composite piece of legislation and includes provisions on organ donation and transplantation, post-mortem practices and procedures, anatomical examination and public display of bodies after death. The Bill has several aims:

1. To support and increase organ donation and transplantation in Ireland by introducing a soft opt-out system of consent. This is where consent for organ donation is presumed *deemed* unless the person has, while alive, registered their wish not to become an organ donor after death. The Bill also introduces frameworks for living donation, including non-directed altruistic donation.
2. The Bill aims to address 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 providing for regulation of post-mortems in hospital settings.
3. 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.
4. Finally, the Bill includes provisions for the governance of the public display of bodies in Ireland.

The original impetus of the Bill was to respond to the recommendations of the Madden Report (2005) to ensure consent was obtained for hospital post-mortems and tissue retention. However, it was decided to include in the Bill provisions related to organ donation, anatomical examination and public display of human tissue due to the current lack of a legal framework for procedures and practices in these areas.

The principle of consent underlies all Parts of the Bill and provides that consent is a pre-requisite for all procedures. However, the type of consent and how consent is applied differs depending on the designated activity regulated for under the Bill, that is:

- the removal, donation and use of organs and tissue from deceased and living persons for transplantation;
- practice and procedures for post-mortems in hospital settings;
- conditions and regulations for anatomical examination; and,
- conditions and regulations for the public display of bodies after death.

Table 1 below outlines the specific treatment of consent across the various provisions of the Bill.

Table 1: Consent in the Human Tissue Bill 2022

Procedure	Type of Consent	Meaning	Potential Donor	Requirements for confirmation or consent	
Transplantation Part 2, Ch. 1	Deemed consent S.17	The individual has **not registered an objection** to becoming an organ donor on the Organ Donation Opt-Out Register.	Deceased Adult	Confirmation that there is no objection to transplantation activities by the designated family member. This must be confirmed in writing, in the presence of a witness. S.10(1)	Where the designated family member cannot confirm in writing, confirmation may be given orally in the presence of 2 witnesses.
	Appropriate consent (also can apply to post-mortem examination) S.2(a)	Consent provided without duress or coercion.	Deceased adult not registered on the Register where deemed consent does not apply.	Consent by the designated family member in writing and signed in the presence of a witness who shall attest to the person's signature. Part 2.	
			Deceased child	Consent by a parent or guardian.	
			Living adult donor of organ or tissues and cells.	Consent by the donor.	
			Non-directed altruistic donor of organ.	Consent by the donor and approval by Panel.	
			Regenerative tissues and cells by a living child.	Consent by parent or guardian, with the approval of the Panel.	
			Regenerative tissues and cells by a living adult who lacks capacity.	Consent by the specified family member with the approval of the Panel.	
			Subject of Post Mortem/anatomical examination/public display		

Post-mortem Activities Part 3, Ch. 1	Post-mortem consent S.38	The consent of a person to post-mortem activities.	Deceased adult	Confirmation that the deceased person had consented prior to their death to a post mortem examination. S.41(1) If not, the designated family member must consent. S.46(2)	Shall be in writing and shall be signed by the person giving the consent in the presence of one witness who shall attest the person's signature. Information to aid understanding of the proposed activity must be provided, as well as information on what subsequent use of any organ or tissue retained.
			Deceased Child	Consent from a parent or guardian.	
			Foetus	Consent from the mother of the foetus or person acting on her behalf.	
Anatomical Examination Part 4	Anatomical consent. S.60	An anatomical examination shall not be carried out unless the institution is in receipt of a consent.	Adult person	Specified by the Medical Council, must be in writing, signed by the person in the presence of at least one witness and include, *inter alia*, confirmation of being furnished and understood appropriate information.	
Public Display Part 5	Consent to donation of body etc. for public display activities S.82	A person shall not use a body for purposes of public display activities without consent in respect of that body.	Adult person	Specified by the Medica Council, must be in writing, signed by the person in the presence of at least one witness and include, *inter alia*, confirmation of being furnished and understood appropriate information	

Source: L&RS, adapted from the Bill's provisions

If enacted, Table 2 shows which bodies will have stated administration, regularity or oversight responsibilities under the Bill:

Table 2: Bodies responsible for regulatory functions under the *Human Tissue Bill 2022*

Regulatory Function	Body
Establishment and maintenance of the Opt-Out Register for Organ Donation.	HSE/Organ Donation & Transplant Ireland
Ensuring compliance with the consent provisions (transplantation).	Health Products Regulatory Authority
Independent assessor for altruistic living donation, and for the living donation of regenerative tissue from children or adults who lack capacity.	Independent Panel
Ensuring compliance with the post-mortem provisions.	Health Information & Quality Authority
Licencing of Anatomical Examination and Public Display of Bodies	Medical Council
Ensuring compliance with consent provisions and inspecting licensed premises (Anatomy, Public Display)	Medical Council

Source: L&RS, adapted from the Department of Health (2019) Regulatory Impact Assessment of the Human Tissue (…) Bill 2022.

Introduction

The *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022* (hereafter referred to as the "Human Tissue Bill" and/or "the Bill") was published on the Oireachtas website, following its initiation, on 20 December 2022. The Bill, a "composite Bill" [1], seeks, among other things, to provide for the following separate, designated activities:

- the removal, donation and use of organs and tissue from deceased and living persons for transplantation;
- practice and procedures for post-mortems in hospital settings;
- conditions and regulations for anatomical examination; and,
- conditions and regulations for the public display of bodies after death.

The Bill seeks to provide a legislative framework for the operation of organ donation and organ transplant services in the State. In addition, it introduces a regulatory regime for the conduct of post-mortems in hospital settings to be overseen by the Health Information & Quality Authority (HIQA), as well as providing for measures in relation to the practice of anatomy and the public display of bodies.

The General Scheme of the Bill was published on 2 May 2019, with the Bill receiving Cabinet approval on 29 November 2022. Talking about the Bill, the Minister for Health, Simon Donnelly TD, stated:[2]

> "[T]he Bill will embed in legislation the idea that consent is the defining principle across all these sensitive areas and will establish a regulatory framework for the conduct of these activities.
>
> "A key priority for me in bringing forward this legislation is to support organ donation and transplantation in Ireland and to make organ donation 'the norm' in situations where the opportunity arises. This Bill will help achieve this through the introduction of a soft opt-out system of consent and pathways for living organ donation and altruistic donation, all of which will help increase the donor pool in Ireland."

Minister Donnelly continued: [3]

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[1] The term "composite Bill" is used in the Minister's press release and also in the Explanatory Memorandum for the Bill. The L&RS could find no definition of composite bill in respect of legislation in the Irish context. In the UK Parliament, there is reference in debates to composite Bill as follows: "This is a composite Bill which is in the nature of an omnibus Measure, and the Clauses are not precisely related to each other" (from Clause 4.—(ADMISSION OF PERSONS AS SOLICITORS.) (Hansard, 11 May 1956) (parliament.uk). Thus the term "composite bill" as used here refers to the fact that the Bill deals with several distinct areas under the broader umbrella of the treatment of human tissue i.e. Organ donation/transplantation, Post-Mortem, Anatomical Examination and Public Display.

[2] Department of Health, 'Minister Donnelly to publish the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill', *Press Release*, 29 November 2022.

[3] Ibid.

> "The Bill also recognises the need to introduce safeguards to protect the integrity of the human body before and after death. Crucially, it will implement the recommendations of the Madden Report regarding consent provisions while the independent regulatory regime being established will help to ensure that the new best practice guidelines being developed by the HSE are complied with by every hospital across the country."

The Bill is comprised of six parts accounting for 105 sections. The substantive parts of the Bill deal, in turn, with "Transplantation" (Part 2, 25 sections); "Pathology Practice" (Part 3, 20 sections); "Anatomical Examination" (Part 4, 22 sections); and "Public Display" (Part 5, 18 sections).[4]

Across these provisions, the Bill provides for - among other things - the following:

- The removal, donation and use of tissues, organs and cells from deceased and living persons for the purpose of transplantation;
- The set-up and upkeep of a register of persons who do not wish to donate certain organs following death;
- The establishment of a panel of persons to oversee certain proposed donations;
- The carrying out and regulation of post mortems in hospitals;
- The donation by living people of their bodies after death for anatomical examination or public display;
- The establishment of the licensing regime for those involved in anatomical examinations and public display;
- That consent is required prior to all procedures involving human organs, tissues and cells, and for all procedures involved with anatomical examination and public display of "human tissue";
- The protection of bodily integrity of all persons before and after death;

The Bill introduces a new framework for the above activities, and as such, is primary legislation. In addition, it also seeks to amend the following Acts and Regulations:

- *Medical Practitioners Act 2007;*
- *Coroners Act 1962;*
- *European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006;*
- *European Union (Quality and Safety of Human Organs intended or Transplantation) Regulations 2012*.

Finally, the Bill seeks to repeal the *Anatomy Act 1832*.

Structure of Bill Digest

Given the size of the Bill, this Bill Digest does not seek to treat each provision but focuses on the main policy issues that the Bill proposes to provide for. As such, the Bill Digest begins by outlining the policy background and context for the Bill and then proceeds in turn to explore each of the following themes treated by the Bill.

- Consent and human tissue
- Organ donation and transplantation
- Post-mortem practice and procedure
- Anatomical examination
- Public display of bodies

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[4] The other Parts of the Bill are Part 1 - Preliminary and General (8 sections) and Part 6 – Miscellaneous (6 sections)

While the Digest is structured around these areas, it focuses on the concept of consent, the key underlying principle defining the practices relating to human tissue treated across the Bill and its various provisions. The principle of consent speaks to the policy and legislative issues central in the requirement for and development of the Bill.

The Digest reviews the pre-legislative scrutiny of the Bill and examines what the Bill provides for in the Principal Provisions. Finally, the Digest looks at relevant commentary on the Bill and the possible implications, including financial, arising from the enactment of the Bill.

Policy context and Background for the Bill

This section traces the background and the policy context to the development of the Bill. This will inform the nature and content of the Bill, and the Digest will examine, in turn, how each of the main themes is provided for by the Bill.

The Bill contains many aspects and seeks to create and update a legislative framework in areas that are on the one hand extremely sensitive and on other, very prescriptive.

These requirements stem not only from advances in technical and medical capacities and the potential medical needs of patients[5] but also from societal consideration of the importance of issues at the legislation's core, namely the treatment of the human tissue of adults and children, both in life and in death.

Another backdrop for the legislation was the publication of the Madden Report (*on Post Mortem Practice and Procedures)* of 2005, responding to the retention of organs and human tissue of deceased persons without seeking family permission. The current Bill reflects the culmination of efforts over a considerable period to respond legislatively to the issues raised and recommendations made in the Report.[6] For this reason, some of the analysis and commentary below draw on the findings and recommendations of the Madden report.

While the Bill in part responds to the recommendations of the Madden Report (2005), it is also adressing other policy issues. The Bill also aims to increase organ donation, and subsequent transplantation, while recognising the changed scientifical, medical and feasibility contexts of these activities. It also recognises the lack of a legal framework and regulations around the use, treatment and display of human tissue in the State.

Before looking in more detail at these developments and themes, it is worthwhile to outline the definition of Human Tissue.

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[5] For instance, the WHO has stated that the "[c]ontinuous improvements in medical technology, particularly in relation to organ and tissue rejection, have led to an increase in the demand for organs and tissues, which has always exceeded supply despite substantial expansion in deceased organ donation as well as greater reliance on donation from living persons in recent years." World Health Organization (2010) WHO guiding principles on human cell, tissue and organ transplantation.

[6] Deirdre Madden, *Report of Dr. Deirdre Madden on Post Mortem Practice and Procedures Presented to Mary Harney T.D., Tánaiste and Minister for Health and Children on 21st December 2005* (Dublin: Stationary Office, 2006).

Human tissue has been defined as an organ, or part of the human body or any substance extracted from a human body.[7] This is a broad definition that, as written, goes beyond organs alone to include a wide array of human tissues that could potentially be taken out of living or dead persons. Human tissue also consists of anything derived from a human being, including blood and blood products, tissue, cells, urine, sputum, faeces etc.[8]

Organ retention and lack of consent

While the "scandals" surrounding organ retention and the related media coverage on the lack of consent and communications with next of kin have some connection to organ donation and transplantation, they are entirely different issues and are provided for separately in the Bill. It also should be noted that the Madden Report on Post-Mortem Practices and Procedures was, as its title suggests, focused mainly on hospital post-mortem examinations.

Organ retention issues in the UK – Impact on Irish debates

The Bristol Inquiry in the United Kingdom was established to inquire into the management of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1998 and 2001. Under its ambit, it emerged that organs had been removed from the bodies of deceased children during post-mortem examinations and had been stored or used for a variety of purposes - including audits, medical education and research - without the consent of their respective parents or guardians[9]. It was subsequently established that Alder Hey Children's Hospital in Liverpool and Birmingham's Diana Princess of Wales Children's Hospital had also been collecting organs and tissues from children who had died in their care without the consent of their parents.[10]

The media attention focused on this issue in the United Kingdom prompted questions as to whether similar practices occurred in Ireland. A parent of a child who had died in Our Lady's Hospital for Sick Children in Crumlin (Crumlin Children's Hospital) contacted the hospital on 12th February 1999, querying whether her child's organs had been retained without her permission. On 12 September 1999, it was reported in a national Sunday newspaper that children's organs had been retained at Crumlin Children's Hospital, with the issue then raised in an RTÉ news bulletin on 7th December and then, on 9th December in Dáil Éireann.[11] The then Minister of State at the Department of Health and Children, Dr Tom Moffatt, reported that a total of 98 children's organs had been retained by Crumlin Children's Hospital, adding that,

> "The chief medical officer of my Department has today written to the chief executive officer of each health agency asking them to ensure, pending the issue by the faculty of pathology of its guidelines on this matter, that a policy of informed consent by next of kin to the

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[7] From the website of New South Wales and the Department of HealthHuman tissue (nsw.gov.au).

[8] From the website of the University College London on the Human Tissue Act -Human Tissue Act | UCL Human Tissue Biobanks - UCL – University College London.

[9] Madden, *Post Mortem Practice and Procedures*, 19.

[10] BBC News, *Organ Scandal Background,* 29th January 2001.

[11] Oireachtas Debates, *Adjournment Debate - Organ Removal and Retention*, Thursday, 9 December 1999, Dáil Éireann Debate Vol. 512 No. 5.

> carrying out of a post-mortem and retention of tissue or organs operates in each health agency. Each agency has also been asked to make appropriate arrangements to deal with any organs or tissue which have been retained and in a manner which is sensitive to the needs of individual families."[12]

Over 200 affected parents formed the *Parents for Justice* advocacy group in 1999 to establish what had happened to the organs of their deceased children at post-mortem examinations.[13] The then Minister for Health, Micheál Martin T.D., subsequently announced an inquiry into post-mortem examinations and organ removal and retention at Crumlin Children's Hospital. Ann Dunne, Senior Counsel, was appointed Chairperson of the Inquiry (later to be referred to as the Dunne Inquiry), which was authorised by Government in April 2000.

Dunne Inquiry 2000-2005

The Dunne Inquiry was established to "review all post-mortem examination policy, practice and procedure in the State since 1970, and in particular, as it relates to organ removal, retention, storage and disposal by reference to prevailing standards both in and outside of the State."[14]

However, the government at the time was unwilling to commit to either a statutory or public inquiry to examine post-mortem organ removal and retention. A two-stage inquiry was agreed:

- A private inquiry chaired by Anne Dunne SC (the Dunne inquiry); and
- An inquiry by a committee of the Dáil.

It has been reported that significant problems were encountered by the Dunne Inquiry:

- The terms of reference[15] were wide-ranging and included a review of all post-mortem examination policies, practices and procedures in the State since 1970, in particular, as it

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[12] Oireachtas Debates, Organ Removal and Retention, 9 December 1999

[13] This group has since been disbanded following an investigation commissioned by the Health Service Executive (HSE) discovered that they had allegedly failed to follow agreements over how some of its funding was to be used. See Eilish O'Regan, *Parents for Justice are criticised for fund misuse,* The Independent, 21 November 2011

[14] Terms of Reference of the Dunne Inquiry.

[15] **Dunne Inquiry Terms of Reference:** To review all-post mortem examination policy, practice and procedure in the State since 1970, and in particular as it relates to organ removal, retention, storage and disposal by reference to prevailing standards both in and outside of the State. To examine the application of these policies, practices and procedures in hospitals, generally and in particular their application in the hospitals listed.

The inquiry will address the hospitals' policies, practices and procedures in this area of organ removal, retention, storage and disposal, the necessity for such practices and the manner in which they were carried out. The inquiry will take account of best practice regarding post-mortem examinations in and outside of the State together with the reasonable expectations of parents of deceased children and next of kin In such circumstances. In particular, the inquiry will:

(a) examine the hospitals' policies and practices relating to obtaining consent from parents and next of kin for post-mortem examinations, organ removal, retention, storage and disposal.

(b) examine the hospitals' procedures and practices relating to retained organs, including the reasons for such retention, the hospitals management of such retention and storage of organs (including record keeping) and of any other arrangements relating to such organs and the practices adopted for ultimately

related to organ removal, retention, storage and disposal by reference to prevailing standards both in and outside of the State. This was for both adult and child post-mortems, and for coronial (coroner's) and hospital post-mortems;
- It had a constricted six-month deadline for the production of a final report. One of the criticisms of the Dunne inquiry was that it repeatedly missed reporting deadlines. Work continued for over four years without reaching any conclusion;
- The Parents for Justice Group and many affected parents withdrew support for the inquiry in 2002 when it became clear that the envisaged Oireachtas inquiry, to follow the Dunne Inquiry, would not take place. The Supreme Court decision of April 2002 in relation to the Oireachtas Abbeylara inquiry effectively rendered any further inquiry by a committee of the Oireachtas questionable in terms of the impact of its recommendations and its powers of investigation.
- It was reported that there were apparent tensions between the government and the inquiry Chairperson.

On 31st March 2005, the Dunne Inquiry was concluded following a Government decision to that effect. The Chairperson delivered a report examining three Dublin-based paediatric hospitals to the then Tánaiste and Minister for Health, Mary Harney, which constituted 3,500 pages accompanied by 51 boxes of appendices, including submissions from parents/guardians, hospitals, health boards and professional bodies[16]. On the advice of the Attorney General, this report was not published. However, a redacted version of an Executive Summary was released under the Freedom of Information Act on 14th February 2008 following an internal Department of Health review.[17]

The Madden Inquiry and Report 2005

Dr Deirdre Madden, a professor of medical law and ethics in University College Cork, was appointed by Government on 3rd May 2005 to inquire into post-mortem practice and organ retention. Like the Dunne Inquiry, Madden's Terms of Reference (ToR) required it to investigate

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dealing with retained organs including any arrangements with pharmaceutical companies in relation to those retained organs;

(c) review the nature and appropriateness of the hospitals' overall response to parents of children and next of kin of persons on whom a post-mortem examination was performed.

(d) examine any specific cases in any hospital as it deems appropriate in relation to post-mortem examinations and post-mortem examination related matters. However, it will be at the discretion of the inquiry to examine any other relevant matters which arise in the course of the inquiry in relation to post-mortem examination policy, practice and procedure in the State since 1970.

In these Terms of Reference post-mortem examination refers to any post-mortem examination including, where appropriate, any post-mortem examinations directed by the Coroner.

The inquiry will make its final report, including its findings, to the Minister for Health and Children within six months unless otherwise determined by the Minister. It will make recommendations to the Minister on any changes it considers necessary on foot of its findings. The report will include confirmation that the inquiry received all the information and co-operation from health agencies, persons employed therein and any other persons, which it considered necessary to form its opinions and to arrive at its conclusions. In the event of deficiencies arising in these areas, which the inquiry considers materially, limited the scope of its investigations the report will identify same.

[16] Deirdre Madden, *Report of Dr. Deirdre Madden on Post Mortem Practice and Procedures Presented to Mary Harney T.D., Tánaiste and Minister for Health and Children on 21st December 2005* (Dublin: Stationary Office, 2006)

[17] Formerly available at: http://www.dohc.ie/other_health_issues/pmpp/execsumm_redacted.pdf

the policies and practices relating to the removal, retention and disposal of organs from children who had undergone post-mortem examination in Ireland since 1970. The inquiry was also asked to investigate allegations that pituitary glands had been removed from children undergoing post-mortem and sold to pharmaceutical companies while examining professional practice in relation to information provided to parents and guardians and the appropriateness of approaches to parental consent.[18] The Madden Inquiry was further required to make recommendations for legislative or policy change in a final report for submission to the Government by 21st December 2005.

Why were parents not told about organ retention?

The Madden Report concludes that, up to 1999, parents were generally not told that organs might be retained at a post-mortem examination of their child. The report finds that there are differing perspectives on the reasons why parents were not told of organ-retention practices. In this context, the report stated that it could not reconcile these views in individual cases. The report describes how Doctors stated that they did not tell parents about organ retention for the parents' own good; parents were upset enough already, and they did not need the information. The giving of such disturbing details to distressed and vulnerable parents, it was argued, could be a complex, lengthy and upsetting process, not easily or speedily undertaken.

The Report finds that the above approach contrasts sharply with the views of some parents that, for them, the "worst had already happened" – the death of their child – and that further information could not have added to their upset. The Report noted that "parents are angry and distressed that this practice took place without their knowledge, that their child's organs were retained for various periods of time, and then disposed of in a manner and place unknown to them".

Another reason the report finds for the non-disclosure is that doctors had a different perspective in relation to organs and did not equate organs with the body as a whole. Doctors generally did not see the organs as having any emotional significance once the child was dead – ensuring that the body be released for burial within the timeframe sought by the family was more significant, in their view, than all the organs being replaced in the body for burial. The report concluded that Doctors were trained to pay less attention to the emotional and symbolic aspects of organs and to concentrate on the functional or medical factors.

The report found that Pathologists also held this functional view of organs. They felt that organs, though clearly deserving of respect, could be considered separately from the body and were not essential for the purposes of viewing and burying the body. However, Madden notes that many parents do not share this view and regard the heart or brain as symbolic of their child's spirit and personality. For these parents, the burial of the body without the organs is an affront to their grief and the child's dignity.

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[18] Deirdre Madden, *Report of Dr. Deirdre Madden on Post Mortem Practice and Procedures Presented to Mary Harney T.D., Tánaiste and Minister for Health and Children on 21st December 2005* (Dublin: Stationary Office, 2006)

The report contained specific recommendations in relation to consent or authorisation:[19]

> "The main aim of this Report is to place parents/guardians at the centre of decision-making and control in respect of hospital post-mortem examinations to be carried out on their children. However, for the reasons outlined, the doctrine and language of informed consent is inappropriate here and therefore is not recommended for use in such legislation. The alternative concept of authorisation is to be preferred. This is a stronger and more powerful recognition of the active role and choice of parents in decision-making in relation to post mortems.
>
> Parents must be given the option of authorising a post-mortem examination to be carried out on their child on the understanding that this is being performed to provide further information as to the cause of death and the possible effects of treatment. Some parents may wish to authorise a post mortem without wanting to receive any further information or consultation. Their right not to receive this information must be respected. It must be made clear to them that they can come back with a future request for more information at any time."

The recommendations of the Madden Report relevant to the relevant parts of this Bill are as follows:[20]

- Legislation must be introduced as a matter of urgency to ensure that no post-mortem examination will be carried out and no organ retained for any purpose whatsoever without authorisation.
- Legislation must make clear that a post-mortem examination includes the necessary removal of organs, and this must be explained to parents before they authorise the post-mortem.
- Parents must be informed that the retention of organs may be a necessary part of the post-mortem process, the reasons for retention, the likely retention period and such other information as they require.
- Parents must be informed of the benefit of retained organs for audit, education and research and given the option to authorise retention for such purposes. Parents must also be given choices for subsequent return, burial or cremation of the organs.
- Legislation should provide that where both parents are legal guardians, either parent may authorise the post-mortem examination, and hospitals may legally proceed with one authorisation, although best practice will usually be not to proceed if there are objections from one of the parents.
- The health and safety aspects of the storage, use and disposal of human organs derived from post-mortem examination must be regulated by legislation.
- The supply of human organs to any pharmaceutical company or third party without the knowledge and authorisation of parents, and the approval of hospital management, should be prohibited.

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[19] Deirdre Madden, *Report of Dr. Deirdre Madden on Post Mortem Practice and Procedures Presented to Mary Harney T.D., Tánaiste and Minister for Health and Children on 21st December 2005* (Dublin: Stationary Office, 2006)

[20] Deirdre Madden, *Report of Dr. Deirdre Madden on Post Mortem Practice and Procedures Presented to Mary Harney T.D., Tánaiste and Minister for Health and Children on 21st December 2005* (Dublin: Stationary Office, 2006)

- An appropriate legislative framework must be put in place to govern hospital post-mortems. The legislation should: be a regulatory model that facilitates the update of guidelines to keep pace with medical & scientific developments; set out the purposes for which a post-mortem examination may be performed; set out safeguards for patients and their families; encourage education and research. Penalties must be imposed for non-compliance.
- Although outside the scope of the Report, legislation is urgently required to deal with removal, storage and use of human biological material from the living and the deceased. The legislation should facilitate and encourage medical education and training and approved medical research should be encouraged while maintaining the principle of respect for the donor, the deceased person and the bereaved.
- Legislation should provide for authorisation to be sought from families for the attendance of medical and nursing students at post-mortem examinations.

Other recommendations

Overall, the Madden Report contains 50 recommendations. It noted that while a number of recommendations relate to other post-mortems, namely those carried out on babies who have died before or during birth, minors and adults, a Working Group should be established to deal with the distinct legal and ethical issues not within Dr Madden's terms of reference. Responsibility for the implementation of the recommendations was shared between the then Department of Health and Children, the HSE and the then Department of Justice, Equality and Law Reform.

Report of the Working Group on Post-Mortem Practice 2006[21]

The working group on post-mortem practice, led by Dr Madden, was established in line with her earlier recommendations and published its report in 2006. Its recommendations of relevance to the current Bill are as follows:

- Legislation should clearly set out the circumstances in which a post-mortem examination of a foetus or stillborn child may be carried.
- Legislation should provide that a competent adult may authorise the carrying out of the post-mortem examination while alive.
- The legislation should provide that the competent patient may nominate a representative who is authorised to make a decision in relation to post-mortem examination on their behalf in the event of their death.
- In the absence of a personal directive or a validly appointed representative, authorisation must be sought from the deceased's next of kin.
- Legislation should provide that a person aged between 12 and 16 may authorise a post-mortem examination of their own body after death.
- Legislation should provide that where a mother is below the age of sixteen, it should be presumed that she is competent to give authorisation for a post-mortem on her child unless there is evidence to the contrary.

Amongst the recommendations contained in the Madden report was the need for an independent audit to be carried out of the currently retained organs in all hospitals in the State. Following this recommendation, an independent Audit of Retained Organs (Willis report) was published by the HSE in June 2009.[22] The report showed significant improvements in post-mortem practice in

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[21] Report of Dr Deirdre Madden of Post Mortem Practice and Procedures 2006

[22] Michaela Willis, "Retained organs report" HSE 2009.

Ireland in recent years. In addition, the report validated all 36 hospitals and five universities involved and identified examples of best and excellent practices.

Table 3 below shows a timeline of developments leading up to the Houses of the Oireachtas debates on the *Human Tissue Bill 2022*.

Table 3: Timeline in the development of the Bill post Madden Report in 2005

Year	Event
2000	Dunne Inquiry established.
2005	• Dunne Inquiry wound-up according to government decision. • Dunne reports to government. • Dunne report is not published on foot of advice from the Attorney General • Madden Inquiry established • Madden Report provided to Minister for Health.
2006	• Publication of the Report of the Working group on Post Mortem Practice by the Department of Health [23] [24] • Regulations were put in place in April 2006 to transpose Directive 2004/23/EC on the quality and safety of tissues and cells, which include the requirement for consent prior to the retention of tissues and cells
2007	First Department of Health led public consultation on the development of a *Human Tissue Bill*[25]
2008	• Publication and debate of Private Member's Bill, Human Body Organs and Human Tissue Bill 2008, (Senator Fergal Quinn).[26] • Government approves (23 September) the preparation of the general scheme and heads of a human tissue Bill to regulate the removal, retention, storage, use and disposal of human tissue from deceased persons and consent for the use of donated tissue from both living and deceased persons for the purpose of transplantation and research.[27]

[23] Press Release on the Publication of Dr Deirdre Madden on Post-Mortem Practice and Procedures, 24 January 2006.

[24] Tribunals of Inquiry. – Tuesday, 16 Feb 2010 – Parliamentary Questions (30th Dáil) – Houses of the Oireachtas

[25] Press Release, Human Tissue Bill set to improve Organ Donation rates in Ireland | Cystic Fibrosis (cfireland.ie), 19 July 2022.

[26] Human Body Organs and Human Tissue Bill 2008.

[27] Human Body Organs and Human Tissue Bill 2008: Second Stage. – Seanad Éireann (23rd Seanad) – Wednesday, 1 Oct 2008 – Houses of the Oireachtas

2009	• Second Department of Health led public consultation on the development of a *Human Tissue Bill*[28] • A general scheme for human tissue legislation was published[29] for the human tissue legislation • HSE published an independent audit of retained organs and post mortem practices in Irish hospitals[30]
2010	• Publication of the General Scheme of the Human Tissue Bill 2010[31] • European Directive on the Quality and Safety of Organs Intended for Transplantation (EU Directive 2010/53/EU), of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation
2012	Publication of S.I. No. 325 of 2012, European Union (Quality and Safety of Human Organs Intended For Transplantation)
2013	Third Department of Health led public consultation on the development of a *Human Tissue Bill*[32]
2014	• The HSE established Organ Donation Transplant Ireland (ODTI) as the delegated body responsible for the implementation of the obligations applicable to the HSE under the Directive and national regulations. • S.I. No. 198 of 2014, European Union (Quality and Safety of Human Organs Intended for Transplantation) (Amendment) Regulations 2014
2015	ODTI publish survey research, commissioned by ODTI, Irish Donor Network and Irish Kidney Association, on public attitudes to organ donation. 81% of respondents indicated willingness to donate organs to an organ donation service immediately after their death.[33]
2017	• Fourth Department of Health led public consultation on the development of a *Human Tissue Bill*[34] • Publication of the Report on the Public Consultation Process on Proposals for a *Human Tissue Bill*[35]

[28] Human Tissue Bill set to improve Organ Donation rates in Ireland | Cystic Fibrosis (cfireland.ie)

[29] Formerly available at: http://www.dohc.ie/issues/human_tissue_bill/report_general_scheme.pdf?direct=1

[30] Michaela Willis, "Retained organs report" HSE 2009

[31] Tissue Bill will have implications for donations (imt.ie)

[32] Press Release, Human Tissue Bill set to improve Organ Donation rates in Ireland | Cystic Fibrosis (cfireland.ie), 19 July 2022.

[33] IPSOS, Organ Donation & Transplant Ireland Research, 2 March 2015.

[34] Press Release, Human Tissue Bill set to improve Organ Donation rates in Ireland | Cystic Fibrosis (cfireland.ie), 19 July 2022.

[35] Report on the Public Consultation Process on Proposals for a *Human Tissue Bill*, December 2017.

2018	Publication of General Scheme of the *Human Tissue (Transplantation, Post-mortem, Anatomical Examination and Public Display) Bill 2018*.[36]
2019	• Re-publication of the General Scheme of the *Human Tissue (Transplantation, Post-mortem, Anatomical Examination and Public Display) Bill.*[37] • Pre-legislative scrutiny hearing of the Oireachtas Joint Committee on Health in respect of the General Scheme of the *Human Tissue (Transplantation, Post-mortem, Anatomical Examination and Public Display) Bill 2018*[38]
2020	*Human Tissue (Transplantation, Post-mortem, Anatomical Examination and Public Display) Bill* included in Government Legislation Programmes for Dáil Sessions.
2021	*Human Tissue (Transplantation, Post-mortem, Anatomical Examination and Public Display) Bill* included in Government Legislation Programmes for Dáil Sessions.
2022	• Publication of HSE internal audit report on "Review of the operation of HSE standards and recommended practices for post-mortem services" [39] • Approval by Cabinet (29 November) and publication on the Oireachtas website (21 December) of *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination, and Public Display) Bill 2022* [40]
2023	Houses of the Oireachtas to begin debate on the *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination, and Public Display) Bill 2022*[41]

Source: L&RS from various sources (as referenced)

Internationally, many jurisdictions have extensively reviewed their post-mortem practices over the past two decades. This was done in response to organ retention scandals, and because of a general shift away from a more paternalistic approach to medicine.

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[36] *Human Tissue (Transplantation, Post-mortem, Anatomical Examination and Public Display) Bill 2018*

[37] Press release, Minister for Health welcomes Government approval to publish Human Tissue Bill (www.gov.ie) 2 May 2019.

[38] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[39] HSE internal audit report on "Review of the operation of HSE standards and recommended practices for post-mortem services"18 February 2022.

[40] Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022 – No. 121 of 2022 – Houses of the Oireachtas.

[41] Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022 – No. 121 of 2022 – Houses of the Oireachtas.

Generally, the express authorisation or consent of the deceased or a next of kin will be needed before organs can be removed and retained. Different jurisdictions place a different emphasis on who can give consent to organ removal, and to how much information must be given to the next of kin in relation to the post-mortem process.

Consent

As previously noted, consent is a central principle underpinning the approach of the Bill across its various parts. This section explores the various conceptions of consent and their relevance to the subject matter of the Bill. The differentiation of consent and the requirements attached to obtaining consent differ sharply between the separate activities dealt with in the Bill.

It is well established in Irish case law and medical ethical standards that consent must be obtained for medical examination, treatment, service or investigation. The requirement for consent is also recognised in international and European human rights law and under the Irish Constitution. [42] This requirement is rooted in the need to respect a person's right to self-determination and autonomy.

In the context of health more broadly, consent has been defined as:[43]

> "Consent is the giving of permission or agreement for a treatment, investigation, receipt or use of a service or participation in research or teaching (intervention). Consent involves a process of communication about the proposed intervention in which the person has received sufficient information to enable them to understand the nature, potential risks and benefits of the proposed intervention."

Valid[44] consent is therefore considered to be the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication about the proposed intervention and should occur as an on-going process rather than a once-off event.

Valid consent requires that a person must:[45]

- Have received ***sufficient information*** in a comprehensible manner about the nature, purpose, benefits and risks of an intervention/ service or research project
- Be *acting* ***voluntarily*** (not under undue pressure/duress from anyone)
- Have the ***mental capacity*** to make the particular decision

However, the issue of consent is complicated. In the past consent was seen to be implied if the next of kin did not expressly object to the removal and retention of organs. Now, many jurisdictions have moved to require either explicit "authorisation" or "informed consent" from the next of kin before organs can be removed or retained. [46]

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[42] Tusla, "National Consent Policy" 2013.

[43] HSE National Consent Policy (2022).

[44] Valid is the state of being officially legally binding or acceptable, HSE (2022) National Consent Policy

[45] Paraphrased from HSE National Consent Policy (2022).

[46] European Directorate for the Quality of Medicines and Healthcare (EDQM) (2022) Guide to the quality and safety of organs for transplantation, 8th Edition, EDQM: Strasbourg.

Consent and Organ Donation

The concept of "opt-out" consent applies solely to organ donation and transplantation. It does not apply to the other parts of the Bill (post-mortems, anatomical examination and public display), which instead utilise a concept of consent referred to as "informed consent". Text box 1 below outlines the particular approach to consent proposed in the Bill solely for organ donation.

Text Box 1: Consent and Organ donation

Under the proposed system of consent for organ donation only, an adult person's consent will be deemed (presumed) unless a person has, while alive, registered their wish to *opt out* of organ donation. A person will be able to record their wish to *opt out* of organ donation by signing up to the Register. If a person has recorded their wish to *opt out* of organ donation, their organs will not be available for transplantation. It is envisaged that a person can remove their name from the Register at any time, should they wish to do so. If a person has not recorded a wish to *opt out*, their consent will be deemed (presumed) to have been given for organ donation. It will be considered that, by not opting out, the person has no objection to becoming an organ donor. However, even if a person has not opted out, the "designated family member" will be consulted about donating the deceased person's organs. If they object, the person's organs will not be donated.

Currently, in Ireland, when a potential organ donor is identified, the deceased person's next-of-kin is asked for their consent to allow organ donation to take place, regardless of the wishes of the deceased before their death. Therefore the decision to donate rests with the next of kin of the deceased. This includes situations where the deceased had decided to donate by, for example, having an organ donor card or indicating their wish to become an organ donor on their driving licence.[47]

There are debates about the implications of the different types of consent. Table 4 outlines in broad terms the differences between the policy options available in choosing one form of consent over another in relation to organ donation and transplantation in the context of the *Human Tissue Bill 2022*.

Table 4: Policy options in respect of consent for organ donation/transplantation only

Types of consent	Variations	Description
Opt-out *Sometimes called* ***presumed consent***	Hard opt-out system *without exemption*	Doctors can remove organs from every adult who dies – unless a person has registered to opt out. This applies even if relatives know that the deceased would object to donation but had failed to register during life. Example: Austria.

[47] Code 115 is placed on Irish Driver's Licences for those who wish to indicate their preference to donate their organs following their death. See Licence Categories and Codes - National Driver Licence Service (ndls.ie)

The person is presumed to have consented to donate his/her organs unless he/she has specified otherwise.	Hard opt-out system *with provision for exemptions*	Doctors can remove organs from every adult who dies – unless a person has registered to opt out OR the person belongs to a group that is defined in law as being against an opt-out system. Example: Singapore where Muslims chose to opt out as a group.
	Soft opt-out *without family consultation*	Doctors can remove organs from every adult who dies – unless a person has registered to opt out OR the person's relatives tell doctors not to take organs. It is up to the relatives to tell the doctors because the doctors may not ask them. Example: Belgium.
	Soft opt-out *with family consultation*	Doctors can remove organs from every adult who dies – unless a person has registered to opt out. It is good practice for doctors to ask the relatives for their agreement at the time of death Example: Spain.
	Soft opt-out With Family veto	Doctors can remove organs from every adult who dies – unless a person has registered to opt out with the confirmation from a designated family member. (System proposed by the Human Tissue Bill 2022)
Opt-in *Sometimes called explicit consent* The person can decide in advance to consent, or to nominate someone to make the decision on his/her behalf after death. Where the deceased has not made a decision his or her family may do so.	Soft opt-in system *with family veto*	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. It is normal practice to let relatives know if the person has opted in and doctors will not proceed if faced with opposition from relatives. Example: Ireland (***currently***)
	Soft opt-in system *with family consultation*	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. It is normal practice to let relatives know if the person has opted in and doctors can decide not to proceed if faced with opposition from relatives, although they have the legal entitlement to proceed according to the individual's wishes. Example: UK
	Hard opt-in system *without family consultation*	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. Relatives are not able to oppose the person's wishes.
Mandated choice /required consent A system of mandated choice	Soft mandated choice system	People are asked to register their choice to opt in or opt out at specified points and CAN choose whether to do so or not.
	Hard mandated choice system	People are asked to register their choice to opt in or opt out at specified points and MUST choose one option.

would require people to exercise a choice whether or not to donate.		
	Required Request	A system of required request would require that a person's wishes MUST be determined before death. Potential donors are identified in hospital Accident and Emergency Departments and Intensive Care Units and the individual or his / her family must be approached and their wishes in relation to organ donation determined.

Source: L&RS, adapted from documentation provided by the Department of Health.

The opt-out, or presumed consent, system of organ donation works on the basis that people are presumed to be willing donors unless they express otherwise to a relevant authority while living. The system of presumed consent is operated in a number of European countries and it has been suggested that, in general, countries with the opt-out system have a better ratio of donors versus people on transplant waiting lists than countries with the more conventional opt-in system. Critics of presumed consent state that it interferes with an individual's right to autonomy and warn that there may be a public backlash against organ donation as a result.

The opt-in or informed consent system of organ donation is a voluntary one and has been described as a system which respects an individual's right to autonomy. It is also an altruistic system, i.e. people donate their organs for the sake of others without expecting anything in return. However, there still remains a discrepancy between the public's expression of willingness to donate and actual donation rates. Another criticism of the opt-in system is that relatives can override the previously expressed wishes of the deceased.

There is evidence to suggest a correlation between the opt-out 'deemed' (presumed) consent and higher rates of organ donation.[48] In a systematic review published in the *British Medical Journal,* Rithalia et al (2009) found that "presumed consent law or practice was associated with increased organ donation." The studies included in the review identified increases of between 21-30%, or between 2.7 - 6.14 more donors per million population (PMP).

However, other research suggests that there may be more to this apparent success than the opt-out consent system alone. Farbe (2014) argues that offering the opportunity to opt-out under presumed (or in the case of this Bill, "deemed") consent is not sufficient as the absence of an objection cannot be taken as informed consent.[49] While populations routinely support organ donation in high proportions, a small fraction registers their intent to donate in an opt-in consent

[48] Organ shortage: current status and strategies for improvement of organ donation – A European consensus document, Council of Europe; Rithalia, A. et al (2009) Impact of presumed consent for organ donation on donation rates: a systematic review*, British Medical Journal;* 338:a3162 https://www.bmj.com/content/338/bmj.a3162

[49] Fabre, J. (2014) "Presumed consent for organ donation: a clinically unnecessary and corrupting influence in medicine and politics", Clinical Medicine Journal, 14(6), pp. 567-571

system. Therefore, the requirement for explicit consent reduces the 'donor pool'.[50] Thus under an opt-out consent system, the donor pool would naturally increase.

As will be shown below, most of the countries with the highest deceased organ donor rates also have presumed consent legislation, and several studies have attempted to determine whether presumed consent, on its own, increases the donor rate. Although some studies have shown that presumed consent "is associated with increased donor rates even when other factors are accounted for[51]," most analyses conclude that investment in other aspects of donation must also be implemented in order to both improve donor rates.[52] [53] [54] In general, countries with high organ donation rates have invested in health infrastructure, focusing on patient identification and referral, public awareness as well as in-hospital teams dedicated to donation and transplantation. Thus, it would seem that investment in other aspects of donation would need to be implemented in line with consent systems to increase donation rates.

Turning to role of family and next of kin in 'overruling' or vetoing organ donations from their deceased, in some jurisdictions, the rate of "family overrule" is over 10%.[55] In the opt-out consent system proposed by this Bill, the family/next of kin (discussed in the Principal Provisions section below) would still retain the right of veto even where the deceased had indicated prior consent for organ donation.

There are many arguments offered in support of allowing family veto:

- It minimises family distress and staff stress;
- It encourages families to cooperate in order for the donation to take place;
- Families might have evidence regarding their decision to refuse the donation;
- and failure to permit this veto to the family may damage trust in the donation system. [56]

The arguments against giving the family a veto include:

- The potential to violate the patient's wishes;
- The question of the appropriateness of placing this responsibility on a family member when distressed and the possibility of regretting the decision;
- This may reduce donations.[57]

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[50] Consent for Organ Donation in Canada - HillNotes

[51] Rithalia, A. et al (2009) Impact of presumed consent for organ donation on donation rates: a systematic review*, British Medical Journal;* 338:a3162 https://www.bmj.com/content/338/bmj.a3162

[52] Raza, F., Neuberger, J. (2022) "Consent in organ transplantation: putting legal obligations and guidelines into practice". *BMC Med Ethics* 23, 69

[53] Consent for Organ Donation in Canada - HillNotes

[54] Parsons, J. A. (2021) "Deemed consent for organ donation: a comparison of the English and Scottish approaches", *Journal of Law and the Biosciences*, 1–16

[55] Shaw D et al (2017) ELPAT Working Group on Deceased Donation. "Family Over Rules? An Ethical Analysis of Allowing Families to Overrule Donation Intentions". *Transplantation*. 101(3):482-487.

[56] Shaw D et al (2017) ELPAT Working Group on Deceased Donation. "Family Over Rules? An Ethical Analysis of Allowing Families to Overrule Donation Intentions". *Transplantation*. 101(3):482-487.

[57] Shaw D et al (2017) ELPAT Working Group on Deceased Donation. "Family Over Rules? An Ethical Analysis of Allowing Families to Overrule Donation Intentions". *Transplantation*. 101(3):482-487.

Legal and regulatory frameworks – Ireland and other jurisdictions

As noted above, there is currently no comprehensive legal framework in the Irish context for the treatment and regulation of human tissue.

The *European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations*, which transpose EU Directive 2010/53/EU, came into effect, in Ireland, on 27 August 2012. The Directive provides the legal framework for organ donation and transplantation in the European Union in the context of quality and safety. At present, the Health Products Regulatory Authority (HPRA) is the competent authority under the EU's Regulations for the authorisation of donation and transplantation in accordance with the requirements of the Regulations. The Health Service Executive (HSE) is the competent authority for quality and safety aspects of the Regulations. The responsibility for this competency has been delegated by the HSE to Organ Donation Transplant Ireland (ODTI) (ODTI is discussed below).

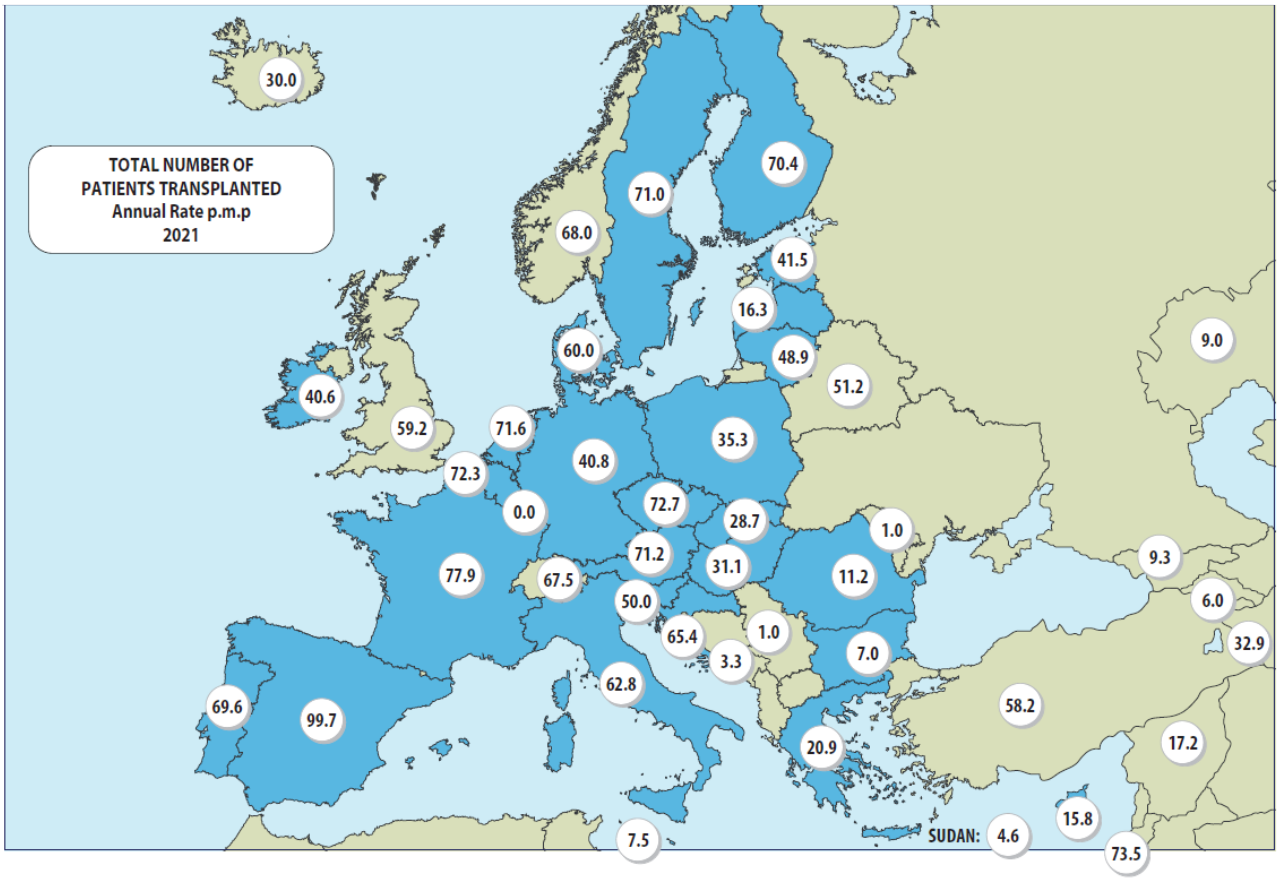
The legal and regulatory regime across EU Member States in respect of organ donation and consent is not strictly comparable.[58] EU Member States have different systems in place to seek people's consent to donate their organs after death. These include both the 'opt-in' and the 'opt-out' system. Some countries have donor and/or non-donor registries. In addition, as is evident in Ireland, there is the possibility for citizens to possess a donor card to indicate donor preference.

Currently, Ireland has an opt-in system for organ donation and no national donor registry. Therefore when a potential organ donor is identified, the deceased person's next of kin is asked for their consent to allow organ donation to take place. This is also as 'express consent' or an 'opt-in' process to becoming an organ donor. Crucially, the choice and the decision to become an organ donor lies with the next-of-kin of the deceased - including in cases where the deceased person had an organ donor card or had indicated their wish to become an organ donor on their driving licence.

Figure 1 below shows the number of transplantation patients per million of population (PMP) across European States as of 2021. It shows that while Ireland had a rate of 40.6 PMP, a significant number of EU States had much higher rates, most notably Spain 99.7, France 77.9, Czech Republic 72.7, Belgium 72.3, Netherlands 71.6 PMP and so on. The UK had a PMP for 2021 of 59.2. There are other States with PMP rates lower than Ireland, however many of these have lower economic per capita income than Ireland. Overall, as noted by stakeholders in the pre-legislation scrutiny hearing on the Bill (discussed further down in this Digest), Ireland's organ and transplantation systems are relatively underdeveloped by comparable international standards.

[58] Statement on transplant and donation figures for 2020, future legislation and vaccine reprioritisation – Irish Kidney Association (ika.ie)

Figure 1: Transplantation patients per million of population in European States 2021



Source: L&RS adapted from Organ donation and transplantation (europa.eu)

Table 5 below shows the various systems of consent for organ donation used in European States as of 2019. It shows 13 States have a registry for organ donors and 21 have a registry for those who do not want to be an organ donor. 21 States operated an opt-out consent system (one State uses a mixed system) and 8 States have an opt-in consent system in place.

Table 5: Systems of Consent for organ donation across EU states in 2019

Flag	EU Member State	Consent system	Donor registry	Non-donor registry
	Austria	Opt-out		✓
	Belgium	Opt-out	*	✓*
	Bulgaria	Opt-out		✓
	Croatia	Opt-out		✓
	Cyprus	Opt-in	✓	
	Czech Republic	Opt-out		✓
	Denmark	Opt-in	✓	✓
	Estonia	Opt-out	✓*	✓*
	Finland	Opt-out	n/a	n/a
	France	Opt-out		✓
	German	Opt-in		

	Greece	Opt-out		✓
	Hungary	Opt-out		✓
	Ireland	Opt-in	n/a	n/a
	Italy	Opt-out	✓	✓
	Latvia	Opt-out	✓	✓
	Lithuania	Opt-in	✓	✓
	Luxembourg	Opt-out	n/a	n/a
	Malta	Opt-out	✓	
	Netherlands	Opt-in	✓	✓
	Poland	Opt-out		✓
	Portugal	Opt-out		✓
	Romania	Opt-in	✓	
	Slovakia	Opt-out		✓
	Slovenia	Mixed	✓	✓
	Spain	Opt-out	✓	✓
	Sweden	Opt-out	✓	✓
	United Kingdom	Opt-out[59]	✓	✓

n/a: data not available
* The data regarding the existence of (non-)donor registries taken from the data source for this table differ from the results of a 2019 EDQM survey. Main data source:
Source: Adapted by L&RS from Organ donation and transplantation (europa.eu) / Guide to the quality and safety of organs for transplantation, EDQM, Council of Europe, 2018 (as adapted from the Commission's 2017 study on the uptake and impact of the EU action plan)

Certain of these countries, in particular Spain, Austria and Belgium, have succeeded in significantly increasing organ donation rates since moving to an 'opt-out' system. However, others have been less successful, such as Bulgaria and Luxembourg, which have some of the lowest deceased organ donation rates in Europe.[60]

In their systematic review, published in the British Medical Journal, Rithalia et al (2009) concluded that while the 'opt-out' system of consent was associated with increased donation rates "it cannot be inferred from this that the introduction of presumed consent legislation per se will lead to an increase in organ donation rates."[61]

As noted in the earlier section, an 'opt-out' system of consent is recognised as just one facet in a suite of measures (all of which must be adequately resourced) needed for organ donation rates to

[59] What is the opt out system? - NHS Organ Donation; UK laws - NHS Organ Donation

[60] Willis, B. H., & M. Quigley (2014) "Opt-Out organ donation: on evidence and public policy", *Journal of the Royal Society of Medicine*: 2014, Vol. 107 (2)

[61] Rithalia et al. (2009) "Impact of presumed consent for organ donation rates: a systematic review", *BMJ* 338:31-62

improve. A previous Minister for Health, Simon Harris T.D., referred to this at an earlier press release on the 'opt-out' system of consent for organ donation:[62]

> "The further development of organ donation and transplant services is a key part of the Sláintecare Action Plan. "I strongly believe that this opt-out system could transform organ donation in Ireland. In order for it to be most effective, it will be supported by a series of other measures. It is so important we do everything we can to make organ donation the norm in Ireland when people pass away in circumstances where donation is a possibility."

Other vital elements include the development of organ donation infrastructure and capital investment in transplant centres. Professor Jim Egan, Director of ODTI in the organisation's annual reports highlighted the need for greater investment in transplant services: *"An increase in organ donation infrastructure would save many lives. In an international context such developments in Ireland are long overdue."*[63]

The importance of investing in infrastructure is a common theme in the literature also:

> "For any organ donation system to be effective, it requires an effective procurement system which is underpinned by a well-organised infrastructure. This is necessary irrespective of the legislation. As a result, focusing on legislative change is to perhaps miss the target if greater gains could arise through organisational and structural change."[64]

Organ donation and transplantation

Part 2 of the Bill, "Transplantation", provides for legal changes in respect of organ donation and their subsequent transplantation. As it stands, when someone dies, the ultimate decision to donate their organs lies with their family, regardless of the expressed wishes of the person before their death. In Ireland, the organs in the main that are donated are heart, lungs, pancreas and kidneys. Broadly speaking, a potential donor has to be in hospital and maintained on a life support machine (such as a ventilator) before they can become an organ donor. A person's organs can be donated after brain stem death or cardiac death.[65] [66]

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[62] Department of Health Press Release, *Minister for Health Welcomes Government Approval to Publish Human Tissue Bill*, 02 May 2019 https://health.gov.ie/blog/press-release/minister-for-health-welcomes-government-approval-to-publish-human-tissue-bill/

[63] ODTI Annual Report 2018, Director's Statement, Pp. 4 https://www.hse.ie/eng/about/who/acute-hospitals-division/organ-donation-transplant-ireland/publications/organ-donation-and-transplant-annual-report-2018.pdf

[64] Willis, B. H., & M. Quigley, *Opt-Out organ donation: on evidence and public policy,* Journal of the Royal Society of Medicine: 2014, Vol. 107 (2)

[65] organ-donation-leaflet-english.pdf (hse.ie)

[66] ***Brain stem death*** means that there is no blood flow or oxygen to the brain. The brain is no longer functioning. There is no hope of recovery. The patient cannot breathe without the help of the ventilator. Doctors carry out tests to confirm brain stem death. Two sets of tests are carried out. The time of death recorded on the death certificate is when the second set of brain stem tests have been completed. **Cardiac death** happens after an illness or injury from which a patient cannot recover. The patient is not brain dead, but has no hope of recovery. The patient cannot survive without the support of a ventilator and medication. Cited from organ-donation-leaflet-english.pdf (hse.ie)

In Ireland, Organ Donation and Transplant Ireland (ODTI) has been delegated the regulatory functions assigned to the Health Services Executive (HSE), pursuant to *Statutory Instrument (SI) 325 (2012), European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012.*

In its most recent Annual Report, for 2021, ODTI provides detail on organ donation and transplants for 2020 and the years running up to that. Before looking at the relevant statistics, it is worth noting the commentary at the start of the Annual Report by Professor Jim Egan, Director of ODTI, which is of relevance to the current Bill also:

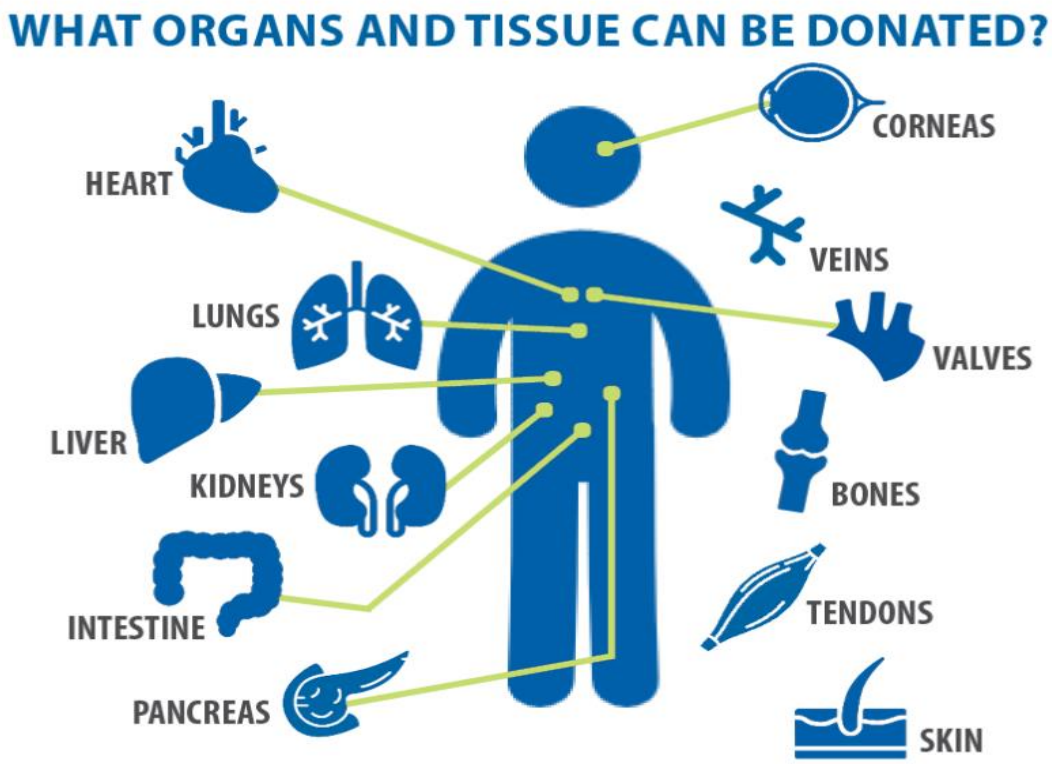
> "As of the year-end 2021, the Human Tissue Bill being drafted by the Department of Health has not yet been published. Consequently, Ireland remains unique, operation donation and transplant services without a National legislative framework.
>
> The absence of the Human Tissue Bill results in Irish citizens who wish to become altruistic doners travelling to the UK to generously donate kidneys to a deserving stranger. Other jurisdictions are investing in organ donation because of the added value of lives saved and cost effectiveness of transplantation relative to the expanding demands for support therapies such as haemodialysis."[67]

Thus, this shows the limited legal framework organ donation and transplantation that has been operating in Ireland to date. It also speaks to the constraints placed on the process by lack of a legal framework and the travel of some donors to make organ donation abroad, as opposed to benefitting patients in Ireland.

Figure 2 below lists all of the organs/tissue which may potentially be donated by a deceased donor. However, Ireland does not provide transplant services for all the organs and tissues listed below.

[67] https://www.hse.ie/eng/about/who/acute-hospitals-division/organ-donation-transplant-ireland/publications/odti-annual-report-2021-final-14-53.pdf

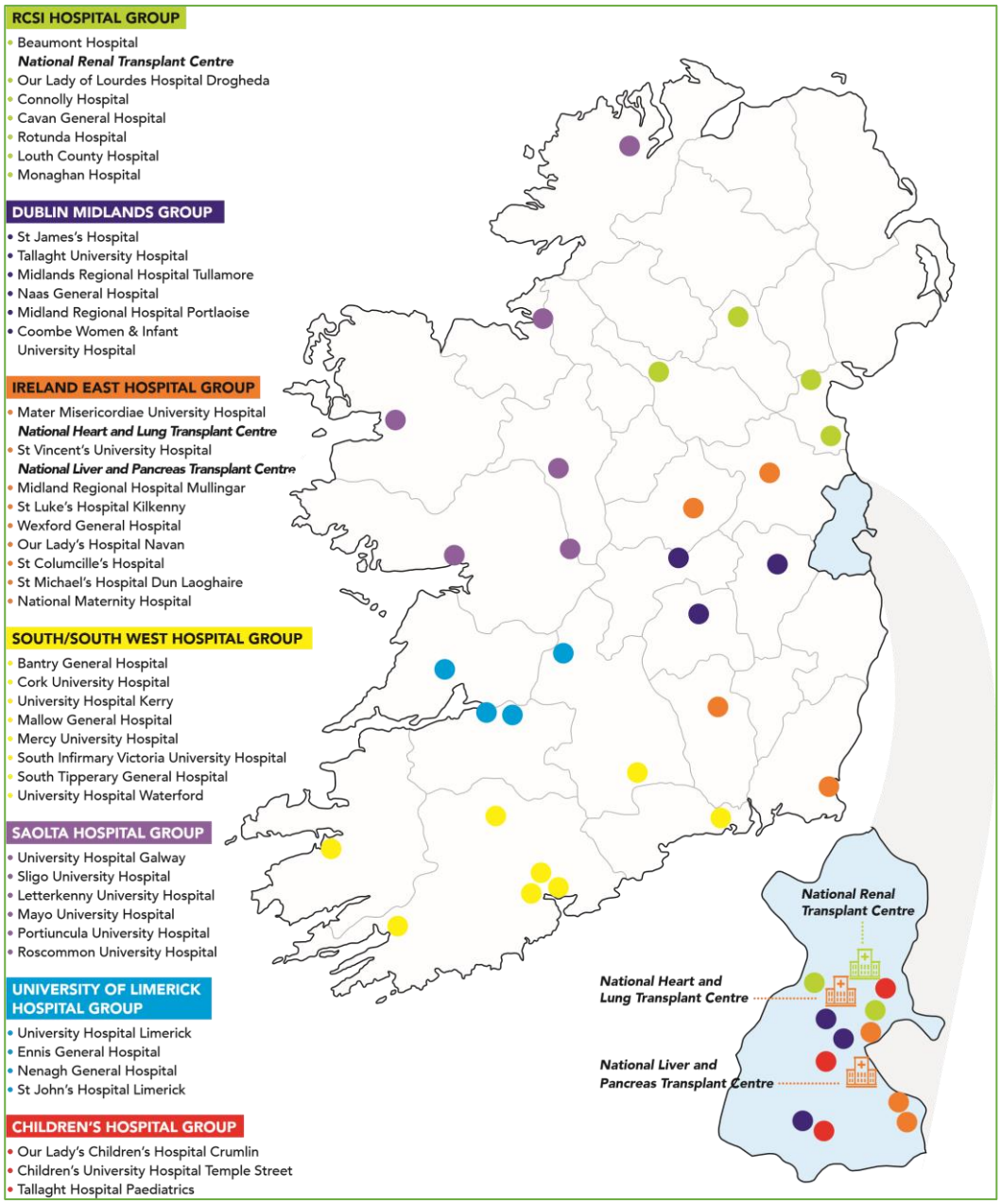
Figure 2: Organs/Tissue that can be donated, where transplantation infrastructure exists



Source: https://www.njsharingnetwork.org/

To make sense of the statistics to follow, Figure 3 below shows the location of the various Hospital Groups under the HSE and also the location of main specialist transplant centres.

Figure 3: Map/graphic of Hospital Groups, their hospitals and transplant centres



Source: ODTI Annual Report 2021

Table 6 below shows the donation activity across hospital groups from 2027 to 2021. It should be noted that the Covid pandemic contributed significantly to a fall off in donor/donation activity in 2020 and 2021. Over the five-year period, from 2017 to 2021, there were a total of 393 organ donations. The highest number was in 2017, with Covid related reductions in 2020 and 2021. Across the hospital groups, the highest number of donations were seen in the RCSI (n114, 29%) and South/South West (n83, 21.1%) Hospital Groups.

Table 6: Donation activity per HSE hospital group and totals, 2017-2021

Hospital Group	2017	2018	2019	2020	2021	2017-2021
RCSI Hospital Group	37	21	23	15	18	114
Dublin Midlands Hospital Group	15	13	11	8	8	55
Ireland East Hospital Group	14	15	15	9	7	60
South/South West Hospital Group	17	15	16	15	20	83
Saolta Hospital Group	6	10	11	9	7	43
University of Limerick Hospital Group	5	6	7	6	4	28
Children's Hospital Group	5	1	2	1	1	10
National annual total	**99**	**81**	**85**	**63**	**65**	393

Source: L&RS, adapted from ODTI Annual Report, 2021.

Table 7 below shows a summary of transplant and organ donation activity over the 2017 to 2012 period. In that time, there were a total of 393 donations from deceased persons. This led to 1,076 organ transplants, with significant numbers of kidney, liver and lung transplants comprising the total. The annual average of donations is 79, while the annual average of transplants over the period is 215. It is worth noting that donations and subsequent transplants were significantly reduced on foot of the constraints associated with Covid 19 precautions.

Table 7: Organ donation and transplant summary 2017-2021

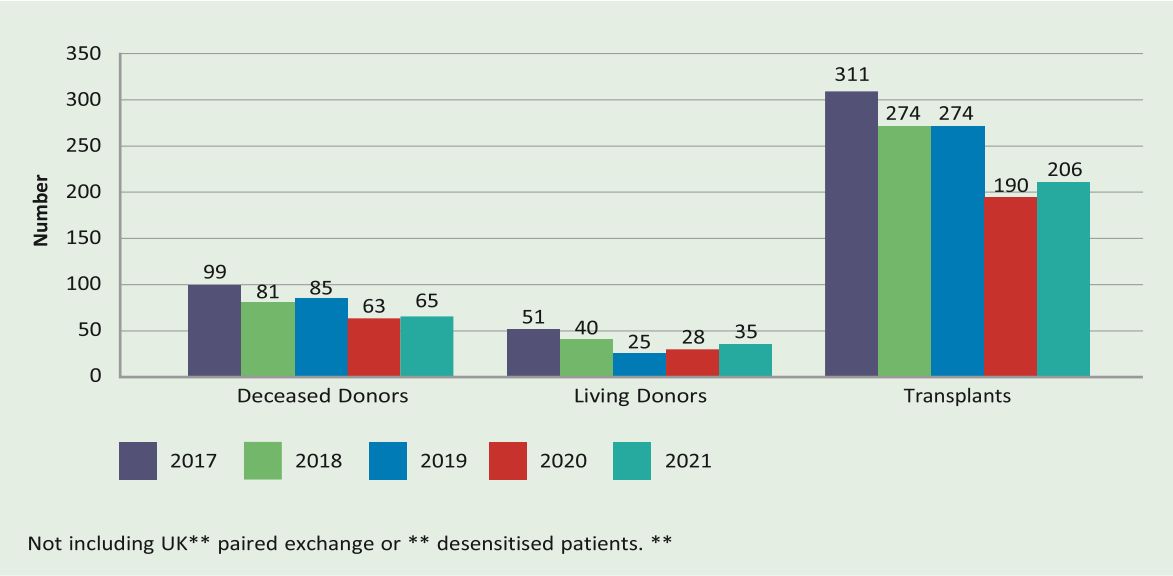
		2017	2018	2019	2020	2021	5 year total	5 year average
Donations		99	81	85	63	35	393	79
Transplant from deceased donations	Kidney	141	127	128	95	104	595	119
	Liver	62	56	66	37	35	256	51
	Lungs	36	28	38	16	20	138	28
	Heart	16	18	15	9	10	68	14
	Pancreas	5	5	2	5	2	19	4
Total		**260**	**234**	**249**	**162**	**171**	**1076**	**215**

Source: L&RS, adapted from ODTI Annual Report, 2021.

Figure 4 below shows that the breakdown of total organ donations between 2017 and 2021 and whether the donation was from a living person or a deceased donor.

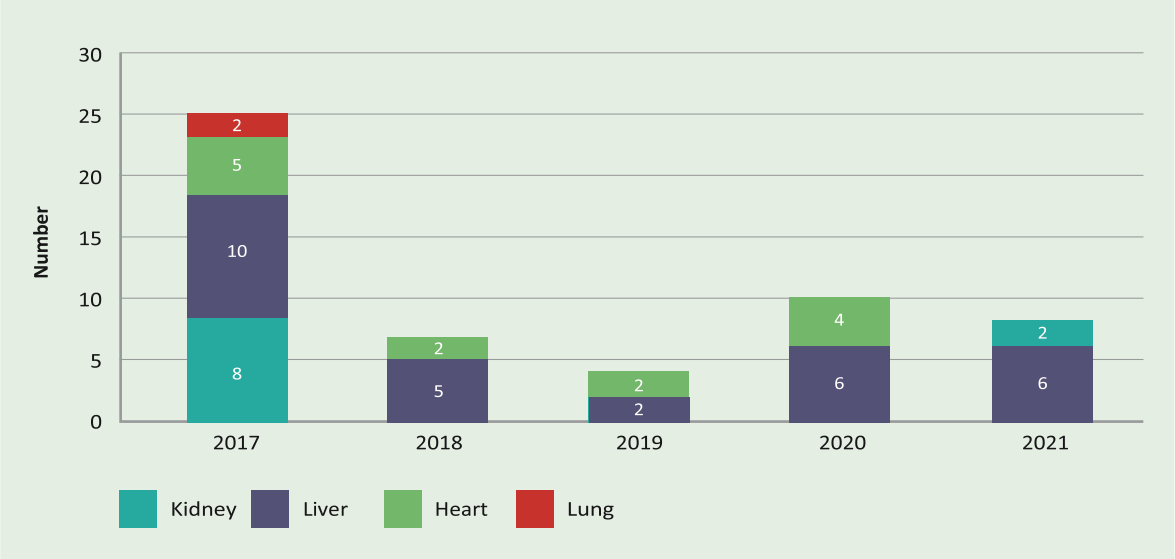
Likewise, Figure 5 below shows that the number of organs utilised outside of the State decreased significantly from 2018 on – it is not clear what impact both Brexit and Covid 19 may have had on this. Importantly there is a provision within the Bill for enhanced cooperation between national health bodies in respect of organ donation for transplantation.

Figure 4: Total organ donations and transplants 2017-2021



Source: ODTI Annual Report, 2021.

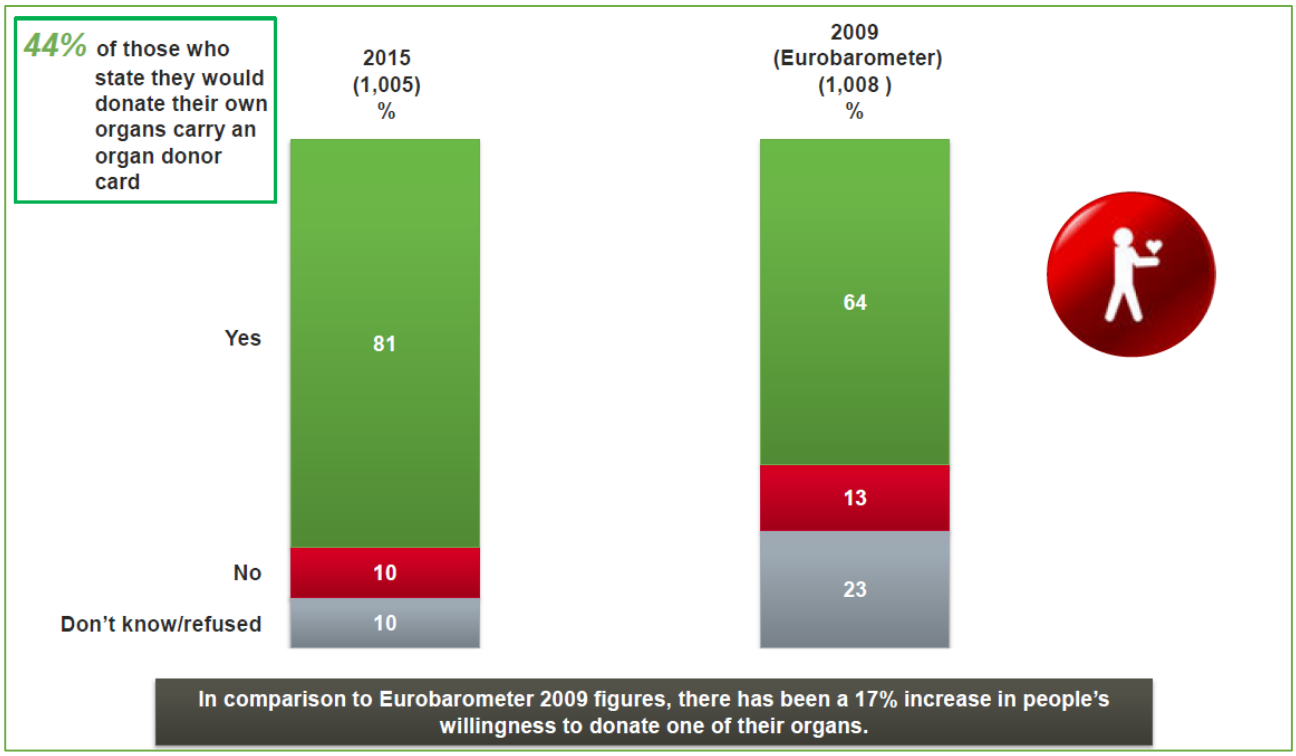
Figure 5: Donated organs utilised abroad



Source: ODTI Annual Report, 2021.

Finally, Figure 6 below shows the results of a national representative survey carried out on behalf of ODTI and other stakeholders in 2015. The survey results show that 81% of people surveyed indicated their willingness to donate their organs following death. Moreover, the survey showed that 44% of this number carried organ donation cards. The survey also recorded that this level of support at 81% had increased from the 2009 survey, where 64% of persons were found to be willing to donate organs. Again, this is in line with findings in other jurisdictions.

Figure 6: 2015 ODTI commissioned survey on willingness to donate organs



Source: IPSOS Mori for ODTI et al, 2015[68]

[68] 15-014021-Organ Donation & Transplant Ireland Omnipoll Research (hse.ie)

Post-mortems and post-mortem practice

Part 3 of the Bill provides for Pathology Practice. A post-mortem examination (also called an autopsy) is a medical examination of a dead body to determine the exact cause of death. It is carried out by a pathologist (a doctor who specialises in the nature and causes of disease). There are two types of post-mortem: one ordered by a coroner (coronial post-mortem) and the other by a doctor (Hospital post-mortem).[69]

A post-mortem examination is, in medical terms, particularly informative and can provide objective information on the cause of death, which is of value to the family of the deceased, healthcare professionals and other interested parties.[70]

From the perspective of the bereaved families, post-mortem examination can also provide information about the risk of inherited diseases, which may benefit family members in seeking necessary care and treatment. Furthermore, family members may be comforted by the knowledge that medical knowledge may be advanced and others helped.

A post-mortem may require that organs are removed in order to further investigate the cause of death. Human biological material (i.e. human tissue) obtained during the course of a post-mortem examination can prove extremely valuable for research purposes. An individual may provide prior consent for the use of their biological material for research. However, this is uncommon. Therefore, the consent form furnished to the next-of-kin prior to a post-mortem examination should include a section which allows relatives of the deceased to give or refuse consent for the use of any retained tissue and/or organs for research purposes.

Text box 2: Two Types of post-mortems are held Ireland

Coroner's (Coronial) Post-Mortems

The Coroner is an independent official with responsibility under law for the medical-legal investigation of certain deaths. He or she is legally obliged to enquire into the circumstances of sudden, unexplained, violent or unnatural deaths. This includes deaths that occur during/after an operation or other medical procedure or deaths within 24 hours of admission to hospital. If the Coroner directs that a post-mortem take place, currently consent is not needed from a parent or next-of-kin. Where performing a coronial post-mortem, a hospital pathologist is acting independently of the hospital, and therefore as an officer of the Coroner.

Hospital Post-Mortem

Where the death of a patient does not require notification to the Coroner or where the Coroner has not directed a post-mortem examination as part an enquiry, post-mortem examination will currently only be carried out with the consent of the parent or guardian. The family may give consent for a complete post mortem examination or may, after discussion with the doctors and medical staff caring for the patient, limit the post-mortem to the examination of a specific region of the body.

Source: L&RS, adapted from the various sources.

[69] Post-mortem examinations (citizensinformation.ie)

[70] HSE Standards and Recommended Practices for Post Mortem Examination Services. QPSD-D-007-1 (lenus.ie)

Coronial post-mortem

The average annual number of deaths over the five-year period from 2015 to 2019 was approximately 31,000. In many cases, the cause of death is known. In these cases, a doctor will fill out the Medical Certificate of the Cause of Death in a straightforward manner. However, in approximately 50-60% of all cases (16,000 to 18,000 cases annually), the cause of death is not immediately known and the case is referred to a Coroner. Deaths from sudden, unexplained, violent, and unnatural deaths must be reported and investigated by the Coroner.[71]

The following is a list of some deaths that are reportable to a Coroner:[72]

- Sudden deaths from unknown causes
- Any case where the cause of death is unknown
- Any accident caused by any vehicle, aeroplane, train or boat
- Where there are suspicious circumstances, violence or misadventure
- Suicide
- If the deceased has not been seen and treated by a registered medical practitioner within 28 days before death
- Due to possible negligence, misconduct or malpractice
- Death occurred within 24 hours of admittance to hospital
- Any death which may have been caused by anaesthetic, diagnostic or therapeutic procedure
- Any maternal death that occurs during or following pregnancy (up to six weeks after birth) or that might be reasonably related to pregnancy
- Any death of a child in care
- Any infant death, such as from Sudden Infant Death Syndrome
- Certain stillbirths
- If the deceased was in a mental health facility, in prison or in Garda or military custody
- Deaths due to want of care, exposure or neglect
- Any death due to accident at work, occupational disease or poisoning
- Where a body is to be removed from the State
- Where a body is unidentified
- In certain circumstances where a body is to be cremated
- Where a body or human remains is “discovered”
- The death of persons in defined vulnerable groups

Table 8: Coroner’s annual statistical report 2021

Area	Report Only	Report and Post-Mortem	Report, Post-Mortem and Inquest	Total cases
Carlow	111	30	15	***156***
Cavan	239	49	29	***317***
Clare	448	38	16	***502***
Cork City	869	245	223	***1,337***
Cork North	268	74	46	***388***

[71] Background Notes - CSO - Central Statistics Office

[72] Information about post mortems (hse.ie) while the above list is comprehensive, it should not be considered all-inclusive.

Cork South	611	121	34	***766***
Cork West	193	64	21	***278***
Donegal	942	145	103	***1,190***
Dublin	6,847	1,688	726	***9,261***
Galway East	306	92	39	***437***
Galway North	70	26	12	***108***
Galway West	845	178	81	***1,104***
Kerry North	61	17	10	***88***
Kerry Southeast	140	33	19	***192***
Kerry West	266	98	25	***389***
Kildare	526	109	65	***700***
Kilkenny	337	108	32	***477***
Laois	206	53	17	***276***
Leitrim	71	19	3	***93***
Limerick	692	109	76	***877***
Longford	89	31	14	***134***
Louth	386	127	89	***602***
Mayo	645	135	43	***823***
Mayo North	82	9	16	***107***
Meath	313	73	44	***430***
Monaghan North	60	23	12	***95***
Monaghan South	47	9	11	***67***
Offaly	225	93	24	***342***
Roscommon	206	14	29	***249***
Sligo	249	110	20	***379***
Tipperary	624	184	60	***868***
Waterford City	462	157	20	***639***
Waterford East	134	26	20	***180***
Waterford West	35	6	7	***48***
Westmeath	314	113	17	***444***
Wexford	530	82	43	***655***
Wicklow East	235	77	25	***337***
Wicklow West	62	9	15	***86***
Total	**18,746**	**4,574**	**2,101**	**25,421**

Source: L&RS, adapted from gov.ie - Coroner's Annual Returns 2021 (www.gov.ie)

Table 8 above shows that in 2021 the State's Coroners dealt with 25,421 cases. Of these, 6,675 involved a post-mortem.

Hospital post-mortem

As noted above, where a death is due to natural causes, and the attending doctor can certify the cause of death, a post-mortem examination, also called an autopsy, is not needed. However, if there is any aspect of a deceased patient's illness needing clarification or confirmation, the relevant treating doctor or the next-of-kin may think a post-mortem is desirable.

If a Coroner's post-mortem examination is not required, a hospital (consent) post-mortem may be requested by Doctors of the next of kin of the deceased. The rationale for hospital post-mortems are:[73]

- To inform Doctors and, therefore, provide the next of kin with more detailed information about the causes of death;
- To contribute to developing new treatments for future patients with similar or related problems.

There are generally two types of hospital post-mortems:[74]

- **Full post-mortem:** This involves a detailed examination of all the internal organs, including the brain, heart, lungs, liver, kidneys, intestines, blood vessels and small glands.
- **Limited post-mortem:** When the next of kin do not consent to the performance of a full post-mortem, they may agree to a 'limited' post-mortem. This involves examining only those organs involved in the deceased's illness. However, this may result in an incomplete or partial assessment and may fail to identify the cause of death and any medical conditions which affected multiple organs.

Table 9 below shows recent HSE data on post-mortems performed in 2021 across individual hospitals. It includes the proportionate split between coronial post-mortems and hospital post-mortems. It is clear that hospital post-mortems accounted for just 2% of the 5,073 post-mortems performed in Irish hospitals in 2021. However, this is not the case in the National Maternity Hospital, Holles Street and Coombe Women and Infants University Hospital, where the majority of post-mortems were hospital post-mortems.

[73] Information about post mortems (hse.ie)

[74] Information about post mortems (hse.ie)

Table 9: Number of post-mortems performed in Irish Hospitals in 2021

Hospital Name	Hospital Group	No. of PMs performed in 2021	% Coroner PM	% Hospital PM
Mater Misericordiae University Hospital (ceased performing PMs since March 2020)	Ireland East Hospital Group	-	-	-
National Maternity Hospital Holles St		27	41%	59%
Our Lady's Hospital Navan		225	100%	-
St. Columcille's Hospital		242	100%	-
St. Vincent's University Hospital		102	100%	-
Coombe Women and Infants University Hospital	Dublin Midlands Hospital Group	45	34%	66%
Midland Regional Hospital Portlaoise		79	100%	-
Midland Regional Hospital Tullamore		237	100%	-
Naas General Hospital		201	100%	-
St. James's Hospital (ceased performing PMs since March 2020)		-	-	-
Tallaght University Hospital		99	100%	-
University Hospital Limerick	University of Limerick Hospital Group	399	100%	-
University Hospital Kerry	South/South West Hospital Group	238	100%	-
University Hospital Waterford		560	100%	-
Cork University Hospital		1,050	96%	4%
Beaumont Hospital	RCSI Hospital Group	123	98%	2%
Connolly Hospital Blanchardstown		207	99%	1%
Our Lady of Lourdes Hospital Drogheda		197	100%	-
CHI at Crumlin	Children's Hospital Group	46	93%	7%
CHI at Temple Street		24	100%	-
Galway University Hospital	Saolta University Health Care Group	428	95%	5%
Letterkenny University Hospital		158	99%	1%
Mayo University Hospital		160	100%	-
Portiuncula University Hospital		80	100%	-
Sligo University Hospital		146	95%	5%
Total		**5,073**	**98%**	**2%**

Source: HSE, 2022.[75]

In the last 12 months, post-mortem practices in some of the country's hospitals have again received media attention placing this sector under intense scrutiny 17 years after the publication of the Madden report. [76] This underlines the need for the Bill to oversee and regulate pathology practices in Ireland.

Anatomical examination

Part 4 of the Bill provides for Anatomical Examination. This is related to the Bill's aim of regulating the removal, retention, storage, use and disposal of human tissue from deceased and living persons. In line with other aspects of the composite Bill, consent is central to its treatment of anatomical examination.

By way of general definition, anatomical examination is where a body or parts of a body, such as organs, are cut apart to allow a person to look at the inside of the body or body part. Anatomical examination may take place as part of research, education or training for health professionals.[77]

Typically, where appropriate legislation is in place, a relevant body is empowered to license and inspect organisations, such as medical schools, that carry out these activities.[78] In the UK, this

[75] Review-of-the-operation-of-hse-standards-and-recommended-practices-for-post-mortem-examination-servicespost-mortem-process-review.pdf

[76] Hospital held organs of child post-mortem for 20 years due to 'ambiguity' over disposal rules (irishexaminer.com): Group probing HSE post-mortem policy to report by autumn (irishexaminer.com)

[77] Frequently asked questions on anatomy and body donation - Human tissue (nsw.gov.au)

[78] Code C.pdf (hta.gov.uk)

body is the Human Tissue Authority (HTA), sponsored by the Department of Health and Social Care as established under the *Human Tissue Act 2004*.[79]

Together with licensing and inspecting the organisations involved in anatomical examination, the HTA also ensure that these licensed organisations remove, store, and use brains, bodies and tissues in an appropriate, respectful and well-managed way, and through the consent system, ensure that the wishes of individual patients and their families are respected.

In the *Human Tissue Bill 2022,* anatomical examination is defined as "the use of a body, or any part of a body, for the purposes of study and practice of the science of anatomy".[80] Licensed institutions under the Bill are those to be licenced by the Medical Council and relevant educational institutions include the Medical Schools of Trinity College Dublin, Royal College of Surgeons in Ireland, University College Dublin, University College Cork and University of Galway.

Public display

Part 5 of the Bill, Public Display, provides for the regulation of display of human tissue in public by the Medical Council. The system of regulation set out is through licensing, referred to as a 'Part 5' licence. The detail of what is proposed in the Bill is set out in the Principal Provisions section of this Digest below.

The context for Part 5 is in broad terms that human bodies, body parts and specimens have to date and may in the future be put on public display. To date, the display of human bodies and tissue of human origin has primarily been carried out by establishments involved in medical education and training and public museums,[81] however, there have been instances of commercially oriented displays of human bodies.

In recent times, there has been some debate about the ethics of displaying human remains and the nature of consent, if applicable, sought. This is particularly apt given the recent issue around the display of the skeleton of a deceased Irish person, Charles Byrne who died in the 18th century, in a museum in the UK for which there was no apparent consent provided.[82] Mr. Byrne's body had been on display for centuries at the Hunterian Museum at the Royal College of Surgeons.[83]

Jones (2013) notes that the public display of human tissue and in particularly human corpses has increased feelings of unease often encountered at the display, whether relating to prehistoric or

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[79] HTA's overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent, in accordance with the provisions of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended). Source: HTA Strategy 2021-2024 | Human Tissue Authority

[80] Section 58, definitions in Part 4, *Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Bill 2022*

[81] HTA Code of Practice D Public Display_1.pdf

[82] Skeleton of 'Irish Giant' to be removed from display at London museum – The Irish Times

[83] Skeleton of 'Irish Giant' to be removed from display at London museum – The Irish Times

recent times.[84] The reasons often stem from what is seen as a lack of respect for the remains of another human being, especially when displayed naked. Jones (2013) argues that while these are legitimate queries, ethical interests extend further to include whether the corpses are identifiable, are prehistoric or recent, and the existence of living descendants. Additional interests include the uses to which corpses are put, namely, research, teaching and/or public displays.

The issue of commodification of, and profiting from, the public display of human corpses is also relevant. In Ireland, there was some debate around the *real bodies* and *body works* exhibitions and questions around if consent was ever received from those whose corpses are now on public display. An article in the Irish Times concluded:[85]

> "Do we still need the display of human remains to help the public understand the human body? The allure of these exhibitions is that they are real bodies rather than models, something that smacks a bit more of sensation than education."

It has been reported in this regard that human remains that had been held for many years by universities or museums being repatriated to indigenous people groups in America, Australia and New Zealand for subsequent reburial.[86] [87]

As can be seen from the above, the public display of human remains is a complex area, with research and educational benefits, but also ethical boundaries and standards that also come into play. Auchter (2018) for instance discusses the way human remains are displayed in the context of memorialisation and as a way of drawing attention to inhumanity. Her particular example is ethical-motivated art projects which seek to highlight the atrocities of the Rwandan genocide.[88]

The purpose of providing for the public display of human tissue is to regulate such activities and ensure certain procedures and standards, such as those relating to consent, storage and handling of human remains used for public display, are met. This is to be implemented through a licensing regime.

In the UK, for example, the Human Tissue Authority is the licencing authority for public display of human bodies. Their regime includes licensing guidelines, exceptions, exclusion of certain human tissue such as gametes, procedures for consent, public registration, time limits where licensing may not apply (e.g. where a body on display is over 100 years old) and so forth.[89]

Under the UK system, there are two licensable activities relating to public display:

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[84] Jones DG, et al.(2013) "The contested realm of displaying dead bodies", Journal of Medical Ethics, Vol 39 No 10

[85] A slice of death: changing attitudes to putting corpses on display – The Irish Times

[86] Jones DG, Whitaker MI, (2009) *Speaking for the dead: the human body in biology and medicine*, 2nd edn. Aldershot: Ashgate.

[87] Jones DG, Harris RJ. (1998) "Archaeological human remains: scientific, cultural and ethical considerations" *Current Anthropology*, 39:253–64.

[88] Auchter, J. (2018). Displaying dead bodies: bones and human biomatter post-genocide. Human Remains and Violence: An Interdisciplinary Journal 4, 1, 41-55

[89] Public display of anatomical specimens FAQs | Human Tissue Authority (hta.gov.uk)

- Storage of the body of a deceased person or relevant material from a human body for a Scheduled Purpose and
- The use, for the purpose of public display, of the body of a deceased person, or relevant material which has come from the body of a deceased person.

In the Human Tissue Bill 2022, public display is defined as:[90]

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

Part 5 of the Bill provides, among other things, for the licensing of public display activities, consent for organ donation for public display, medical certification of death, suspension and revocation of licence, import and export of specimens for public display and the role of the Medical Council as regulator.

[90] Section 81, *Human Tissue […] Bill 2022*

Pre-Legislative Scrutiny of the General Scheme of a Human Tissue Bill

By 2017, the development of a "Human Tissue Bill" had been ongoing for over ten years. The then Minister for Health, Simon Harris, T.D., announced a public consultation on proposals to introduce legislation on the topic. This would encompass post-mortem activities, public display of bodies, anatomical examination and transplantation. Specifically, it would include an 'opt-out' system of consent for organ donation. In a Department of Health press release, the Minister highlighted the main purpose of this Bill, *"to provide a framework of informed consent"*.[91] The General Scheme of the Bill was published on 2 May 2019 and referred to the Oireachtas Joint Committee on Health in the 32nd Dáil for pre-legislative scrutiny (PLS).

The Oireachtas Joint Committee on Health began its PLS in October 2019. Subsequently a PLS hearing was held on 16th October 2019, attended by officials from the Department of Health together with invited representatives from HSE ODTI, Irish Kidney Association and the Irish Donor Network. The General Election of 2020 was called in February 2020, resulting in the dissolution of the Dáil and the Joint Committee on Health before it had the chance to issue its PLS report on the General Scheme of the Bill.

Following representations on the part of the Department of Health in respect of the status of PLS on the Bill, the Clerk of the Oireachtas Joint Committee Health Committee in the 33rd Dáil confirmed through e-mail on 12 November 2020 that the PLS had been completed on the Human Tissue Bill and that "there was broad acceptance of it".[92] Thus, cognisance of the input on the proposed legislation by the Joint Committee on Health during the 32nd Dáil, the Minister for Health sought permission from the Business Committee for a Waiver of the need for the Bill to undergo PLS in the 33rd Dáil. The Dáil Business Committee granted the waiver on 5 February 2021.

While the PLS was not completed in reporting terms by the Oireachtas Joint Committee on Health in 2019, the PLS hearing nevertheless provided good insight into the debates surrounding the Bill and the views of the Members and various stakeholders. The following are some of the themes that were covered in the debate.[93]

Different aspects of consent applying across the various part of the General Scheme

It was evident in the opening statements and during the hearing that the focus was in the main on consent and the related register system in respect of organ donation and transplantation. This

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[91] *'Opt-Out' system of organ donation moves a step closer as Minister Harris announces opening of public consultation on Human Tissue Bill*, Department of Health press release, 28 August 2017 https://health.gov.ie/blog/press-release/opt-out-system-of-consent-for-organ-donation-moves-a-step-closer-as-minister-harris-announces-opening-of-public-consultation-on-human-tissue-bill/

[92] Communication from the Department of Health to the L&RS.

[93] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

reflected the stakeholders invited to the Committee hearing and the prominence of this issue in policy terms vis-à-vis other parts of the General Scheme of the Bill.

However, it was noted that this is just one part of the Bill. In this regard, Professor Jim Egan of ODTI noted the following:[94]

> "There had been a lot of debate on whether the soft opt-out would be a separate piece of legislation. Maybe I am stealing Mr. Conroy's [Department of Health official attending the hearing] thunder here but we have distinct sections in the legislation to address that so Part 2 [of the General Scheme of the Bill] relates specifically to transplant."

Mr. Michael Conroy of the Department of Health confirmed as follows:[95]

> "I mentioned previously the Madden report and that is the background of a Bill on consent for human organs and tissue, which is covered in this. The provisions in respect of post-mortem specifically covers the issues that appeared at that time. It is separate to transplant and they were linking in with anatomical examination, public display and so on [in this General Scheme of the Human Tissue Bill]."

Soft opt-out versus soft opt-in system of consent for organ donation

During the course of the hearing there was a robust debate on the benefit of the proposed opt-out system as opposed to an opt-in process. Officials from the Department of Health and thereafter the Irish Donor Network (IDN) argued in favour of the opt-out scheme while the Irish Kidney Association (IKA) argued in favour of the Opt-in scheme. [96]

In its opening statement, Mr Philip Watt of IDN made the following points in support of the soft opt-out system of consent:[97]

> "While it is always challenging to make direct comparisons with other countries, the decision to bring a soft opt-out system into Ireland follows the success of soft opt-out in many other EU countries, including in Austria, Spain and Belgium. There has also been a strong momentum growing in the UK to introduce soft opt-out in recent years. In England, the Organ Donation (Deemed Consent) Act has passed through the UK Parliament, with implementation due to start in April 2020. This will replace the present on line opt-in and opt-out system that has failed to deliver and which should not be considered for Ireland. Under the existing system in the UK, only 38% of the UK population has registered their wish to opt in on the existing online organ donor register, which is why most UK health bodies concerned with transplant are now seeking to replace this system with the approach

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[94] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[95] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[96] The Irish Donor Network is comprised of the following patient groups: the Alpha One Foundation; Chronic Obstructive Pulmonary Disease Support Ireland; Children's Liver Disease Ireland; Disease Support Ireland; Cystic Fibrosis Ireland; Cystinosis Ireland; the Irish Heart and Lung Transplant Association; and the Irish Lung Fibrosis Association.

[97] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

> that we are advocating for Ireland. The IDN does not want to import an opt-in and opt-out system into Ireland, because this system has clearly demonstrated failure in England."

In contrast to this, the IKA made statements which supported their view of the inherent value of a donor register but questioned the efficacy of the soft opt-out register alongside seeking family consent. At the hearing, Mark Murphy of IKA stated the following:[98]

> "For more than a decade we advocated for the introduction of an organ donor register. This would offer a very clear call to action for the public and can be very easily established in such a way that facilitates the organ donation conversation.
>
> With a register, Organ Donation and Transplant Ireland, ODTI, would have for the first time a central record of an individual's decision to be an organ donor. This would be consulted when a potential donor has been identified and knowing that a loved one had proactively recorded a wish to be an organ donor makes the family decision to consent a much easier proposition.
>
> In putting an emphasis on soft opt-out with family consent, this Bill is misleading the public as it implies a change of practice, whereas the reality is that the practice stays the same. Currently, a potential organ donor is identified, the family is approached and consent for retrieval is either given or not. Under the proposals in this Bill, the public will have the opportunity to opt out of organ donation and if people do not opt out, they will be considered potential donors but the family will still be approached for final consent. Where is the difference?"

Michael Conroy pointed out the practical benefits of the soft opt-out system of consent with family consultation:[99]

> "The proposed soft opt-out system recognises the practical need for family co-operation to obtain social and medical information about the donor. Safeguarding a future potential organ recipient involves the completion of a comprehensive donor lifestyle questionnaire which requires the co-operation of the next-of-kin."

The hearing saw both sets of stakeholders cite research and statistics that highlighted in a nuanced way the benefits of a soft opt-out and opt-in models. However, across all stakeholders at the hearing, there was a shared conviction that although a register of some sort is essential to increasing donor rates, the key was ensuring public education and putting the requisite nursing and clinical infrastructure and personnel in place to implement the process:

Mark Murphy of IKA stated in this regard:[100]

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[98] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[99] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[100] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

> "The experience in other countries shows, even though all the opinion polls show that the public and the key stakeholders are in favour of this change, that it is important that the change is explained to people through a public awareness programme and an education programme. That should be done jointly between ODTI and patient groups to ensure that the message gets across. Any kind of major change in policy has to be carefully explained and understood by the public. That is important."

Professor Jim Egan stated the following also:[101]

> "The threat arising from having a register is that one ends up talking to the converted and that it will be heavy on resources when they need to be targeted at nursing to increase the levels of education and support provided for families. The other potential threat is that it is unlikely we would have a 100% penetration rate across the population. People are, naturally and appropriately, not in this zone. We have heard informally that in other jurisdictions in cases where people had not put their names on the positive register, their families inferred that they did not support organ donation and that they, therefore, should not go ahead and donate. There are some threats in that system. Let us emphasise again that nurses' support for families and education are the jewels in the crown."

Mr. Michael Conroy of the Department of Health mirrored the general sentiment also:[102]

> "We do not think the legislation on its own will cause a jump in numbers. The combination of all the things we are doing and the publicity will do that."

[101] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[102] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

Principal provisions of the Bill

Introduction

This section examines the principal provisions of the Bill most relevant to the main policy changes proposed by the legislation. The Bill is a composite piece of legislation and includes provisions on organ donation and transplantation, post-mortem practices and procedures, anatomical examination and public display of bodies after death. The Bill has a number of aims:

1. To support and increase organ donation and transplantation in Ireland by introducing a soft opt-out system of consent, where consent for organ donation is "deemed" unless the person has, while alive, registered their wish not to become an organ donor after death. The Bill also introduces a framework for living donation, including non-directed altruistic donation.
2. To address the concerns raised in the Madden report by introducing a statutory requirement for consent for non-coronial post-mortems and by providing for regulation of post-mortems in hospital settings.
3. To repeal the Anatomy Act of 1832 and replace it with legislative arrangements governing the donation of bodies to anatomy schools and standards to be met in the practice of anatomy.
4. To provide provisions for the governance of the public display of bodies in Ireland.

Bill synopsis

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

The Bill is divided into 5 Parts, and each part is subdivided into Chapters and Sections:

Part 1 – Preliminary and General
Part 2 - Transplantation: provide general conditions for the removal, donation and use of organs and tissue from deceased and living persons for transplantation

Part 3 -Pathology Practice: regulate practice and procedures for post-mortems in hospital settings
Part 4 -Anatomical Examination: regulate practice and procedures for post-mortems in hospital settings
Part 5 -Public Display: provide general conditions and regulations for public display of bodies after death
Part 6 – Miscellaneous

The Principle of Consent in the Bill

The Bill provides that consent is pre-requisite for all procedures, including the separate activities involving the removal, donation and use of organs and tissue from the deceased and living for transplantation as well as procedures for post-mortems, anatomical examination, and public display of bodies after death.

As this is a composite Bill, it deals with distinct areas under the broader umbrella of "the treatment of human tissue", with the core definition of consent consistent throughout. However, within the Bill, there are two areas where the issue of consent is most significant:

1. The issue of consent regarding organ donation and transplantation. Currently, Ireland has an opt-in system for organ donation and no national donor registry. This legislation introduces a soft opt-out system of consent. This means that once the Bill is law, it is presumed that all people (with exceptions) have consented to organ donation unless they have stated otherwise. However, the final decision on organ donation rests with the designated family member, in what is known as "soft opt-out". This means that even where consent is presumed, the donation would not proceed if the designated family member objected to it.
2. The issue of consent for non-coronial post-mortems as recommended in the Madden Report. There is no legislative framework currently in place and no consistent national policy relating to these practices. The Bill meets all the key recommendations of the Madden Report to create a framework for consent, both for hospital post mortems and for the use or retention of any part of the body for any reason following a post mortem.

Section 2 of the Bill defines consent as the giving of a permission or an agreement, that is voluntarily and freely given or made, for the use of human cells, organs and tissues for the purpose of transplantation activities, post-mortem examinations, anatomical examination or public display. In addition, the person giving consent must have received information sufficient to allow that person to understand the nature, risks, and benefits of the proposed procedure.

Part 2, "Transplantation" chapter 1, section 10 covers the general provisions of deemed consent and appropriate consent.

Part 3, "Pathology Practice" chapter 2 deals with consent and post-mortem activities.

Part 4, "Anatomical Examination" section 60 deals with consent to donate a body for anatomical examination.

Part 5, "Public Display" section 84 deals with consent to donate a body for public display purposes.

Deemed consent

Deemed Consent applies specifically to the donation of specific organs by a deceased adult. Section 17 states that a person shall be deemed to consent to the donation and removal, after their death, of their relevant organs where they have not registered their objection to such organ donation on the Register. Exemptions for deemed consent are listed.

Section 10(1) provides that when deemed consent applies and there is no objection to transplantation activities by the designated family member; this must be confirmed in writing. (emphasis added). Section 17(6) requires the designated family member to consider and give substantial weight to the wishes of the deceased. Significantly, the designated family member is given a veto to object and stop the transplantation activity. This would seem to create an anomaly in the conditions on deemed consent. The aim of an 'opt-out' register is to ensure that the final wishes of adults who do not want to donate their organs are respected and upheld. An adult who has not signed the 'opt-out' register and is not exempt under the conditions is presumed to consent to organ donation. However, the final say rests with the designated family member. A designated family member's objection to organ donation will override any decision made by the deceased to be an organ donor (e.g. if they carry an organ donor card or have agreed to organ donation on their driving licence/learner permit.)

Appropriate consent

Appropriate consent applies to both donation of specific organs and post-mortem consent. Section 2 provides that it is consent provided without duress or coercion.

In relation to transplantation in relation to a deceased adult who is not registered on the Register, where deemed consent does not apply, consent is provided by the designated family member.

In relation to transplantation in relation to a deceased child, consent is provided by a parent or guardian.

In relation to the donation of an organ by a living adult donor or a non-directed altruistic donor, consent is provided by the donor and, in the case of a non-directed altruistic donor, consent is provided with the approval of the Panel.

In relation to the donation of tissues and cells by a living adult, consent is provided by the donor. In relation to the donation of regenerative tissues and cells by a living child, consent is by a parent or guardian, with the approval of a Panel in accordance.

Post-Mortem Consent

Post-mortem consent is a subset of Appropriate consent. In the Bill, Post-Mortem consent is also dealt with individually in Chapter 2.

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. This is in line with recommendations in the Madden report.

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. If this has not been given, consent can be given by a designated family member, who must consider whether they believe that the deceased person would have objected to the post-mortem activities concerned.

The 2005 Madden report also called for legislation to address obtaining consent by a parent for post-mortem activities on a deceased child and this is provided in Section 47 of the Bill. Consent must be given by a parent or guardian of the child, and they must have regard to any previously expressed wishes of the deceased child, in proportion to the child's age, degree of maturity and decision-making capacity. If one parent or guardian should object, any consent that may previously have been given by the other parent or guardian is nullified.

The Bill does not give priority to a "parent" or a "guardian" regarding consent, treating both equally. However, a parent may, in some circumstances, not be the legal guardian. A father who is not married to the mother of his child has automatic guardianship rights in relation to that child where they are cohabiting/have cohabited with the mother and child and meets certain requirements.[103] In addition, guardianship rights may be removed by the court. The rights of parents to guardianship are set down in section 6 of the *Guardianship of Infants Act 1964* as amended. Guardianship rights entitle a parent to make important decisions regarding the child, including medical treatment. The Madden report differentiates between parent and legal guardian, advising that where both parents are legal guardians of a deceased child either parent should be able to give authorisation for a hospital post-mortem examination, though ideally both should participate in the decision. The Bill may avoid confusion by clarifying that the parent making the decision is the legal guardian.

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.

Designated Family Member

Section 7 specifies who can be considered a designated family member when a registered medical practitioner is seeking consent to transplantation or post-mortem examination.

This is significant in relation to transplantation as the designated family member can veto the transplantation if they object.

With "deemed consent" section 17(3) provides that where a person has not registered their objection to the donation of their organs (opt-out) a registered medical practitioner must be satisfied that the designated family member has confirmed that they have no objection to the donation. Section 17(6) states that the family member "shall consider and give substantial weight as to whether or not" they believe the person would have had an objection.

When "deemed consent" does not apply, sections 18 and 19 provides that the medical practitioner must seek "appropriate consent", which includes post-mortem consent, from any designated family

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[103] Section 6B of the *Guardianship of Infants Act 1964* inserted by the *Children and Family Relationships Act 2015.*

member with whom the registered medical practitioner has had real and substantial contact in relation to the care and treatment of the relevant person.

Section 7(10) provides that the designated family member must consider and give substantial weight as to whether or not he or she believes that the relevant person, the subject of the request, would have had an objection to such donation, removal or non-coronial post-mortem examination when considering whether to provide appropriate consent, including post-mortem consent.

For Post Mortem activities, section 46 (2) provides that the designated family member must provide consent if the deceased person had not consented prior to their death. Section 46 (3) provides that they must consider whether they believe that the deceased person would have objected to the post-mortem.

Who is the designated family member?

Section 7(2) provides that a designated family member is, or was immediately before the death of the relevant person:

> (a) a spouse or civil partner of the relevant person,
>
> (b) a cohabitant of the relevant person,
>
> (c) a child of the relevant person,
>
> (d) a parent of the relevant person or a person who was a guardian of the relevant person before that relevant person attained 18 years,
>
> (e) a brother or sister (whether of the whole or half blood) of the relevant person,
>
> (f) a grandparent of the relevant person,
>
> (g) a grandchild of the relevant person,
>
> (h) an uncle or aunt (whether or the whole or half blood) of the relevant person,
>
> (i) a niece or nephew of the relevant person, or
>
> (j) a close friend of the relevant person who can demonstrate to the satisfaction of the person seeking consent or confirmation, as the case may be, that they can determine and accurately convey the wishes of the relevant person concerned.

Adoptees, step children or people who had a longstanding professional relationship with the relevant person are not included in this category and therefore are not included explicitly on the hierarchy of priority. This may potentially cause confusion, for example, if the biological child and the adopted child (both over 18 years old) of a potential donor disagreed about donating their parent's organs.

In addition, the Bill does not explicitly state that the relationships in different paragraphs of section 7(2) are ranked in the order of appearance of those paragraphs. In the Scheme for the Bill, it was stated in Head 6(3) that Relationships in different paragraphs of subhead(1) rank in the order of appearance of those paragraph. The Bill may benefit from this wording. For example in section 7(5) appropriate consent is sought from a person whose relationship to the relevant person is accorded the highest ranking in accordance with subsection (2) (emphasis added).

For appropriate consent, section 7(4) consent may be obtained from any designated family member with whom the registered medical practitioner has had real and substantial contact in relation to the care and treatment of the relevant person. Real and substantial contact is not defined in the Bill.

If section 7(4) does not apply, appropriate consent, must be obtained from a person whose relationship to the relevant person is accorded the highest ranking in accordance with subsection(2). As noted above, it is not clarified how the relevant person is ranked.

Who does not Qualify to be a Designated Family Member?

Section 7(3) details who does not qualify to be a designated person.

Spouses and civil partners are not designated family members if they have separated – requiring that a deed of separation or a decree of judicial separation has been granted, or a written agreement to separate has been made or if they had been separated or ceased to cohabit with the relevant person for a continuous period of at least 12 months.

Those who do not have the capacity to consent, or are under eighteen (other than where they are the parent of that relevant person) also do not qualify to be a designated person.

Section 7(9) provides that the following shall also not be included as a designated person:

(a) the person does not wish to consider whether or not they object or consent,

(b) the person is unable to make a decision whether or not to object or consent,

(c) the person is unable to confirm that there is no objection to deemed consent,

(d) it is not reasonably practicable to communicate with the person in the time available to obtain consent or

(e) the relationship between the person and the relevant person cannot be confirmed for the purpose of this section.

Table 10: Consent in the Human Tissue Bill 2022

Procedure	Type of Consent	Meaning	Potential Donor	Requirements for confirmation or consent	
Transplantation Part 2, Ch. 1 Transplantation	Deemed consent S.17	The individual has **not registered an objection** to becoming an organ donor on the Organ Donation Opt-Out Register.	Deceased Adult	Confirmation that there is no objection to transplantation activities by the **designated family member**. This must be confirmed in writing, in the presence of a witness. S.10(1)	Where the designated family member cannot confirm in writing, confirmation may be given orally in the presence of 2 witnesses.

	Appropriate consent (also can apply to post-mortem examination) S.2(a)	Consent provided without duress or coercion.	Deceased adult not registered on the Register where deemed consent does not apply.	Consent by the **designated family member** in writing and signed in the presence of a witness who shall attest to the person's signature. Part 2.	
			Deceased child	Consent by a parent or guardian.	
			Living adult donor of organ or tissues and cells.	Consent by the donor.	
			Non-directed altruistic donor of organ.	Consent by the donor and approval by Panel.	
			Regenerative tissues and cells by a living child.	Consent by parent or guardian, with the approval of the Panel.	
			Regenerative tissues and cells by a living adult who lacks capacity.	Consent by the specified family member with the approval of the Panel.	
			Subject of Post Mortem/anatomical examination/public display		
Post-mortem Activities Part 3, Ch. 1	Post-mortem consent S.38	The consent of a person to post-mortem activities.	Deceased adult	Confirmation that the deceased person had consented prior to their death to a post mortem examination. S.41(1) If not, the **designated family member** must consent. S.46(2)	Shall be in writing and shall be signed by the person giving the consent in the presence of one witness who shall attest the person's signature. Information to aid understanding
			Deceased Child	Consent from a parent or guardian.	

			Foetus	Consent from the mother of the foetus or person acting on her behalf.	of the proposed activity must be provided, as well as information on what subsequent use of any organ or tissue retained.
Anatomical Examination Part 4	Anatomical consent. S.60	An anatomical examination shall not be carried out unless the institution is in receipt of a consent.	Adult person	Specified by the Medical Council, must be in writing, signed by the person in the presence of at least one witness and include, *inter alia*, confirmation of being furnished and understood appropriate information.	
Public Display Part 5	Consent to donation of body etc. for public display activities S.82	A person shall not use a body for purposes of public display activities without consent in respect of that body.	Adult person	Specified by the Medica Council, must be in writing, signed by the person in the presence of at least one witness and include, *inter alia*, confirmation of being furnished and understood appropriate information	

Source: L&RS, adapted from the Bill's provisions

Other Requirements of Consent

Confirmation/Consent in Writing

Section 10(1) provides that when **deemed consent** applies and there is no objection, this must be confirmed by the designated family member in writing, in the presence of a witness.

Section 10(2)b provides the same requirements for **appropriate consent**.

Post-mortem consent shall also be in writing; however, section 40(1) provides that this must be signed by the person giving the consent in the presence of one witness who shall attest the person's signature.

Anatomical consent is also in writing and similar to post-mortem consent, section 60(4) requires a signature by the person giving the consent in the presence of one witness who must attest the person's signature. In addition, a confirmation is required that the person concerned has been furnished with, and understands the proposed procedure.

All of the above allow the family member to consent or confirm orally in the presence of two witnesses when they cannot confirm in writing for any reason. This allowance was not contained in the General Scheme and has been added as recommended by the PLS.

In section 84(4) the consent to **donation of a body** must be signed by the person in the presence of at least one witness who shall attest the signature and include a confirmation by the person concerned that he or she has been furnished with, and understands, the information about the procedure. However, the allowance to consent orally is not provided in this instance.

Consent and 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, donation for anatomical examination, or public display. This section is subject to the Coroners Acts.

Conditions in relation to donation of organs, and tissues and cells

Chapter 3 sets out the conditions which must be met for the donation of organs and tissues and cells. This covers donation of tissues and cells by living adult donors, donation of organs by non-directed altruistic donors, living adults who lack capacity and living children.

Table 11: Conditions re: donation of organs, tissues and cells

	Organs	Tissues and Cells
Living adult donors	S.22 states information that must be provided. Listed principles that must be adhered. It also identifies the point up to which consent can be amended or withdrawn	S.21 states information that must be provided. Listed principles that must be adhered. It also identifies the point up to which consent can be amended or withdrawn.
Non-Directed Altruistic donors	S.23 states 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	
Living adults who lack capacity	S.24 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
Living Children	S.25 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.

Source: L&RS, adapted from the Bill's provisions

Conditions related to the Removal and Retention of organs and other body parts during post-mortem examination

Section 42 sets out the conditions applying to non-coronial post-mortem examinations. It includes provisions relating to the 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.

Consent and Commercial purposes and consent for use – post-mortems

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.

When Consent is not given – Post-mortems

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.

Transplantation Activities outside of Consent

"Transplantation activities" is defined in Section 11 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.

The principles of organ and tissue and cell donation are provided for in Section 12. 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.

Donation Opt-out Register

Chapter 5 deals with all of the details of the opt-out register.

Section 31 provides that an Organ Donation Opt-Out Register be established and maintained by the Health Service Executive (HSE) (delegated in practice to ODTI under the 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.

In order for an individual to be included on the Organ Donation Opt-Out Register, section 32 details the information that an applicant must provide as part of his or her registration. An individual can amend or withdraw their registration and individuals are prohibited from registering or amending the details of others on the Register without prior consent from the person concerned.

To find out whether a person is listed in the register, section 33 stipulates that a clinician must 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.

Post-Mortem Practice and Procedures outside of Consent

Outside of consent, and the conditions applying to the removal and retention of organs and other body parts during post-mortem examinations, the Bill also covers:

- The purposes for which post-mortem activities may be undertaken in section 43.
- The identification of which medical professional can conduct a post-mortem. The Bill provides in section 44 that post-mortems can be undertaken by a pathologist or a registered medical practitioner under the supervision of a pathologist.
- A report must be prepared following a post-mortem examination and section 45 sets out what information shall be recorded in that report and how the report should be retained.
- A nomination person is required to be appointed by each hospital that conducts post-mortem activities who will serve as the main contact point for the regulator as well as fulfilling other responsibilities as set out. Section 51 also delineates the responsibilities of such "a nominated person" under the Bill.
- The authority to monitor compliance with post-mortem activities and procedures is granted by section 52 to the Health Information and Quality Authority (HIQA). 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.

Anatomical Examination outside of Consent

Part 4 of the Bill provides for regulation on Anatomical Examination. Included in the bill is:

- The requirement for a medical certificate of cause of death must be signed before an anatomical examination can take place. Section 61 also provides that the Medical Certificate of Cause of Death must be retained by the licensed institution which received the body.
- 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.
- The loan or transfer of anatomical specimens for purposes of anatomical examination is permitted. Section 63 provides that the loan or transfer is only permitted between institutions on the island of Ireland and is subject to pre-authorisation from the Medical Council, as the 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.
- Anatomical specimens can be imported for anatomical examination. Section 64 provides that this 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 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*.

Governance of the public display of bodies in Ireland outside of the consent

Part 5 of the Bill covers Public Display Activities. Included in the Bill are the following:

- What is encompassed by the term "public display activities"? Section 81 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.
- The requirement of a licence for public display activities. Section 83 describes conditions that 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.
- Consequences of a breach of these obligations. Exemptions to the requirement for a licence are also provided in section 83.
- 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.
- Sections 86-89 covers the application for a licence (known as a license 5) 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 includes details of the appeals proposal available to the applicant should the Medical Council refuse a request for a licence, the conditions placed on the licence, the

steps the medical council must take to suspend or revoke a licence and how to appeal the decision.

- The loan or transfer of anatomical specimens for the purposes of public display can take place. Section 91 provides that this can be permitted only between licence holders on the island of Ireland and is subject to pre-authorisation from the Medical Council.
- Anatomical specimens can be imported for public display activities. Section 92 provides that this is subject to pre-authorisation from the Medical Council and the Part 5 licence holder must be satisfied that any anatomical specimen has been obtained, transported, used, and disposed of in accordance with any consent given by the donor.
- Records must be kept in relation to anatomical specimens by the Part 5 licence holder. Failure to maintain a document register is treated as an offence under this part of the Bill.
- The Medical Council must monitor compliance with provisions on Public Display of Bodies and they are empowered to act as regulators.

Implications

The main implication of the Bill is the establishment of a comprehensive legal framework for policy areas that had not been formally regulated for in some instances; or were subject to secondary legislation in other instances. To this end, the Bill, if enacted, increases the regulatory and administrative responsibilities of ODTI, the HPRA, IMC and HIQA.

Table 12: Bodies responsible for regulatory functions under the *Human Tissue Bill 2022*

Regulatory Function	Body
Establishment and maintenance of the Opt-Out Register for Organ Donation.	HSE/Organ Donation & Transplant Ireland
Ensuring compliance with the consent provisions (transplantation).	Health Products Regulatory Authority
Independent assessor for altruistic living donation, and for the living donation of regenerative tissue from children or adults who lack capacity.	Independent Panel
Ensuring compliance with the post-mortem provisions.	Health Information & Quality Authority
Licencing of Anatomical Examination and Public Display of Bodies	Medical Council
Ensuring compliance with consent provisions and inspecting licensed premises (Anatomy, Public Display)	Medical Council

Source: L&RS, adapted from the Department of Health (2019) Regulatory Impact Assessment of the Human Tissue (…) Bill 2022.

The Department of Health's Regulatory Impact Analysis (RIA) on the Bill stated that the proposed legislation will largely consolidate and standardise the current practices of medical and nursing staff in relation to transplantations and post-mortems and should not, therefore, give rise to additional implementation and compliance costs.[104]

In order to manage costs relating to the enforcement of the provisions of the Bill, if enacted, agreement has been reached with existing bodies (HIQA, HPRA, Medical Council) to undertake the regulatory roles and functions in the proposed legislation rather than creating a new regulatory body. The introduction of legislation will however incur an increase in operating costs for these bodies.

The Medical Council estimates that their increased responsibilities under the proposed legislation will increase operating costs by approximately €67,000 per annum. The Medical Council is funded primarily via registration and license fees, and these changes may result in an increase in these fees.

The HPRA already conduct inspections in relation to consent for transplant. As such, it is anticipated that any increase in operating costs will be minor, and these will be dealt with through the normal estimates process.

The provisions of the Bill give HIQA the additional responsibility of regulating hospital post-mortems. It is anticipated that costs will not be substantial and will be dealt with through the normal estimates process.

The cost of administration and implementing new responsibilities under the Bill, if enacted, will become clearer over time relative to the assessments made above. However, this is an area which ought to be monitored if the intended aims of the Bill are to be fulfilled. In that event, the quantum of work required of the regulatory authorities will likely increase with knock on effects on their relative resource bases.

In tandem with the above, the data obtained from other jurisdictions that introduced 'opt-out' systems for organ donation show that the legal framework alone will not be sufficient to increase donations. The research shows that public awareness, education and, crucially, the development of organ donation and transplantation infrastructure (nurse specialists, additional clinical resources etc.) were essential elements. This will require resourcing not directly accounted for in cost assessments associated with the Bill as detailed by the RIA.

This was noted by an official from the Department of Health at the PLS hearing on the General Scheme of the Bill in 2019:[105]

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[104] Department of Health (2019) Regulatory Impact Assessment (RIA) of the Human Tissue (…) Bill 2022. Provided to the L&RS by the Department of Health.

[105] Michael Conroy, Department of Health, Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

> "The bit that is not resourced as well as it could be is the retrieval service because people have to retrieve outside their ordinary jobs. … There have been tensions in hospitals over this but a dedicated person for this purpose would be a huge step forward"

Professor Jim Egan of ODTI added:[106]

> "The jewel in the crown is the nurses and the infrastructure to support the family with organ donation. … Other jurisdictions have been working on this for a long time and the Spaniards started in 1989. We have got stuck into it in the past few years but we have a way to go. We need at least €2.1 million, in new money, to target organ donation and transplantation. That would be distributed to the specialist nurses and the retrieval teams and would underpin the education of the relevant stakeholders. I do not count the money for the register in this figure, nor that for the public awareness campaign".

In response to a question on the requirements of additional personnel, Dr Egan commented:[107]

> "There would be about 20 altogether. They would be a mixture of doctors, retrieval surgeons and nurse specialists. Other jurisdictions have invested heavily in this area because there is such a benefit to the health service, particularly in dialysis because we save patients' lives"

The Department of Health acknowledged the resource implications intrinsic for the successful implementation of the policies framed and enabled by the Bill (if enacted):[108]

> "Our hope is that the legislation will bring pressures on us in terms of resources and we recognise that some necessary resources are coming next year".

Finally, Dr Jim Egan of ODTI made comments at the PLS hearings on the General Scheme of the Bill that speak to the overall cost and benefits associated with the Bill's enactment in the context of broader health service and services for people who would benefit from organ transplantation:[109]

> "Appropriate organ donation infrastructure would save many lives and decrease the burden of costly interventions such as dialysis which costs around €65,000 per annum versus approximately €12,000 for kidney transplant surgery."

Stakeholder/media commentary

While there has been little commentary since the publication of the Bill on 21 December 2022 up the time of writing, there has been considerable coverage of the issue in Ireland over a number of years.

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[106] Professor Jim Egan, ODTI Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[107] Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[108] Michael Conroy, Department of Health, Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

[109] Professor Jim Egan, ODTI, Joint Committee on Health debate - Wednesday, 16 Oct 2019 (oireachtas.ie)

In October 2022, the Irish Examiner reported on the case of infant who dies shortly after birth whose remains were incinerated without the knowledge of the family, they quote the mother's request for the provision of a legal framework to constrain similar activities:[110]

> "The mum of a baby whose organs were incinerated without her knowledge is calling on the Government to publish the Human Tissue Bill as quickly as possible, to prevent other families going through the pain she is enduring."

The report went on state that mother is "is currently awaiting a report from the hospital following a review of how his organs, and those of 17 other babies, were sent to Belgium for incineration without the consent or knowledge of their parents".

> "The organs were sent for incineration in late March and early April 2020, to free up space at the hospital morgue because of the possibility of increased deaths because of Covid-19."

In a similar vein, The Journal.ie reported on concerns from stakeholders in respect of the delay in the publication of the Human Tissue Bill in July of 2022:[111]

> "Health advocates fear that legislation providing for soft opt-out organ donation in Ireland could be left off the government's agenda – after it failed to sign off on it this week. They say that attempts at bringing in the legislation began over a decade ago, and that they are frustrated at how long it's taking Ireland compared to our neighbours in the UK."

In the same article, Philip Watt of Cystic Fibrosis Ireland (CFI) and chairperson at the Irish Donor Network was quoted as follows:[112]

> "It's really disappointing it's been delayed. It's been promised in the last three programmes for government."

Mr Watt also said CFI understands that it is not the opt-out section of the legislation that is delaying the Bill, and because of this he has asked the Health Minister to separate those parts out from the rest of the legislation.

Mr Watt added that:

> "if other aspects are delaying the legislation, then the organ donation consent section should be prioritised." "There is a worry that with this latest delay the Bill will fall off the legislative programme again",…"We are languishing well behind best practice in Europe on this," Mr Watt also added.

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[110] Families affected by organ incineration scandal call for Human Tissue Bill publication (irishexaminer.com)

[111] 'It's very worrying': Frustration as Dáil term ends without action on opt-out organ donation (thejournal.ie)

[112] 'It's very worrying': Frustration as Dáil term ends without action on opt-out organ donation (thejournal.ie)

Reflecting on the debate during the PLS of the Bill, the Irish Kidney association, in its statement of 22 November 2022, noted some of the difficulties that media coverage around the Bill has or potentially might create:[113]

> "It is important that when explaining the new legislation to the public that the focus is on not leaving your family in doubt. Headlines such as "Under the bill, consent will be deemed unless a person has, while alive, registered his or her wish to not become an organ donor after death" are already starting to appear which can be misleading.
>
> It is important that the media play its part in communicating that families still play a central role in consenting to organ donation. This will reinforce the value of having the family organ donation conversation before the unthinkable happens.
>
> Under the Driving Licence application process, over one million people have proactively ticked a box to express their consent to organ donation. A very positive number given that there was no publicity around it."

The Irish Independent reported in January 2023 that the IKA said the publication of the bill "is a major step forward in replacing the outdated Anatomy Act 1832", and that:[114]

> "[w]hen transposed into law, how this proposed new legislation will be communicated to the public will be vital in ensuring the public are aware that organ donation is still subject to family consent, unless the loved one has previously opted out by entering details on the proposed new national opt-out register,"

Finally, Orla Tinsley, writing in the Irish Times on 13 December 2022, made the following comments about the imminent Bill:[115]

> "After more than a decade of waiting, the opt-out system of organ donation Bill has been passed in Ireland.[116] This is a signal of progressive and future-thinking politics that seek to honour donors and support those who work to give the gift of life, and the person receiving it.
>
> The soft opt-out policy we are introducing can bring complications and there is scant evidence to support it works better than our current practice. It means, in the past and new legislation, the family has the final say. The soft part relates to your wishes as a donor being ignored and disregarded if your family declines to agree to donate your organs. It's not a hard and binding decision you have made, because your family has the final say. The

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[113] Press Statement on the Human Tissue Bill, Organ Donation for Transplantation – Irish Kidney Association (ika.ie)

[114] 'I believe that by donating a kidney to me, my brother saved my life' - Independent.ie

[115] Orla Tinsley: I am deeply concerned about education around the organ donation opt-out system – The Irish Times

[116] It should be noted, for clarification, that the Bill was only published on 21 December 2022 and is due for Second Stage debate in the Dáil on 24 January 2023.

opt-out relates to everyone automatically being a donor unless you choose, explicitly by registration, to opt-out.”

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