Comhairle na nDochtúirí Leighis
Medical Council

Medical Council's Code of Practice for Anatomical Examination

Human Tissue Act 2024 – Part 4
(Transplantation, Post-Mortem, Anatomical Examination and Public Display)

Section 1: Introduction & Medical Council Overview

Introduction & Purpose

The Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024 was enacted to modernise Ireland's legal framework surrounding the donation, use, and examination of human bodies for anatomical study and other medical purposes. It replaces the Anatomy Act of 1832, a nearly 200-year-old statute that no longer reflected the ethical, scientific, and societal standards of contemporary healthcare.

The Human Tissue Act 2024 (the Act) was introduced to establish a clear, consent-based legal framework for the donation and use of human tissue. It responds to growing public concern about the dignity and respectful treatment of human remains, and the need for robust oversight in education, research, and public display. By consolidating previously fragmented or outdated legislation, the Act ensures transparency, accountability, and ethical governance in all practices involving human tissue.

This Code of Practice (the Code'):

- supports institutions and individuals in the State to apply best practice that reflects current societal, scientific, medical, educational and ethical norms when conducting anatomical examinations.
- helps the public understand the current best practices used by institutions and individuals in the State who conduct Anatomical Examination, thereby promoting transparency, trust, and accountability.

Medical Council Overview

The Medical Council (The Council) is the regulatory body for doctors. It has a statutory role in protecting the public by promoting the highest professional standards amongst doctors practising in the Republic of Ireland. The Council also sets the standards for medical education and training in Ireland.

The **Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024**. was introduced to modernise Ireland's legal framework governing the donation, use, and examination of human bodies for medical and scientific purposes. It replaces the historic **Anatomy Act, 1832** bringing the law into line with contemporary medical practice and ethical standards.

The **Human Tissue Act 2024** is a comprehensive piece of legislation. It addresses organ, tissue and cell donation and transplantation, post-mortem practices and procedures, anatomical examination, and the public display of bodies after death. At its core is a clear and consistent principle: consent. Across all of these sensitive areas, the Act establishes consent as the foundation for lawful and ethical practice.

The Council has a central regulatory role in ensuring the lawful and ethical use of human bodies for anatomical examination and public display under Parts 4 and 5 of the Human Tissue Act 2024. Under Parts 4 and 5 of the Human Tissue Act, the Medical Council has a central regulatory role in overseeing the lawful and ethical use of human bodies for anatomical examination and public display. As the primary regulatory authority in these areas, the Council is responsible for upholding high ethical standards, maintaining public trust, and ensuring the respectful treatment of human remains in educational, scientific, and public settings.

This Code relates specifically to Part 4 (Anatomical Examinations) of the Act. A separate Code of Practice applies to Part 5 (Public Display).

Under Part 4, the Council licenses institutions that carry out anatomical examinations and ensures they meet the statutory requirements set out in the Act. These requirements include appropriate facilities, robust governance arrangements, and suitably qualified personnel. Each licensed institution must designate a responsible person, approved under the Act, who is accountable for ensuring that all anatomical activities are conducted properly and lawfully.

The Council monitors compliance with this Code through regular inspections and record reviews. It ensures that anatomical consent is properly obtained, accurately recorded, and fully respected, and that all activities are conducted with dignity, and in accordance with the law. The Council also has the authority to issue, amend, suspend, or revoke licences, and to attach conditions where necessary to ensure continued compliance.

Definitions (Part 4)

Section 61 provides definitions that shape the legal framework for anatomical examination in Ireland. Understanding these terms is important for ensuring compliance and respectful and lawful handling of human remains.

Definitions, as follows:
"Anatomical Consent" shall be construed in accordance with Section 63.

"Anatomical Examination" The use of a body, or any part of a body, for the purposes of the study and practice of the science of anatomy.

"Anatomical Specimen" A body (including separated parts of such a body) intended for or being used in anatomical examination with this Part; or which is being used for anatomical examination in accordance with this Part

"Applicant Institution" has the meaning assigned to it by Section 68

"Authorised Officer" means a person appointed under Section 79

"Body" means the body of a deceased person

“Licensed Institution” An institution licenced by the Medical Council under Section 68 in respect of the carrying out of anatomical examinations

“Relevant Institution” means the institution to whom the licence has been granted.

“Responsible person” has the meaning assigned to it by Section 65

Section 2: Code of Practice for Anatomical Examinations

Licensed Institutions

An institution licensed by the Council under Section 68 of the Act is formally authorised to carry out anatomical examinations. This licence is issued following an application and inspection process to ensure the institution meets the required legal, ethical, and operational requirements.

The application submitted by the institution seeking a licence must:

- Be in such form and manner as specified by the Medical Council
- Specify the name and address of the applicant institution
- Specify the name of the proposed responsible person and the address of their principal office or place of business
- Specify the qualifications of the proposed responsible person
- Provide details of the facilities of the applicant institution with respect to the activities the subject of the application
- Specify the premises at which it is proposed to undertake anatomical examinations
- Provide such other information, including information regarding the governance of the applicant institution as the Council may specify, and be accompanied by the fee as determined by the Council under subsection 13 of the Act).

A licence will only be issued if the Council is satisfied that examinations will be conducted in accordance with the law and licence terms.

Once an institution is licensed, it operates within a clear and supportive regulatory framework designed to maintain high standards. The Council provides ongoing oversight through regular inspections carried out at least once every three years, as well as compliance monitoring and continued engagement with the Code of Practice. A licence may include specific conditions. Where necessary, the Council can amend, suspend, or revoke a licence if the requirements of the Act or the terms of the licence are not met.

Being a licensed institution carries significant responsibilities, including ensuring that all anatomical examinations are conducted ethically, respectfully, and only with valid consent. It

also means maintaining accurate documentation, records, cooperating with inspections, and upholding public trust in the use of human tissue for education and research.

Section 68 of the Act establishes a licensing framework to ensure that only institutions meeting high standards of professionalism, ethics, and operational readiness are authorised to conduct anatomical examinations. Requiring detailed applications, regular inspections, and ongoing monitoring and compliance with the Code upholds accountability and safeguards the respectful treatment of human remains. Therefore, reinforcing public trust in the anatomical donation system by ensuring that examinations are carried out only in properly regulated environments by qualified personnel.

Responsible Persons

Section 75 of the Act requires every licensed institution to appoint at least one suitably qualified person to act as the Responsible Person for anatomical examinations and related activities. Each institution must make this appointment within 12 weeks of the Act coming into operation.

The Role of the Responsible Person

The Responsible Person is responsible for:

- Conducting and directing anatomical examinations
- Applying to the Medical Council for permission to loan, transfer, or import anatomical specimens
- Keeping the records required under Section 76 of the Act
- Preparing and submitting the institution's annual report to the Council
- Acting as the main point of contact with the Council

The Responsible Person must be named on the licence issued under Section 68 of the Act.

Delegating Responsibilities

The Responsible Person may delegate certain tasks to other suitably qualified individuals. However, they remain accountable to the Council for those tasks. If functions are delegated, the Responsible Person must ensure that:

- Appropriate training is provided and recorded
- Clear accountability arrangements are in place

Appointing a new Responsible Person

If the institution wishes to appoint a new Responsible Person, it must notify the Council and provide the following:

- The person's name
- Their qualifications
- The date the appointment takes effect

The Responsible Person may revoke any delegation made under subsection (4).

An appropriately qualified person is someone with the relevant experience, training, or expertise, to carry out the responsibilities outlined under Part 4 of the Human Tissue Act and to follow any applicable codes of practice.

By requiring each licensed institution to name a qualified individual as Responsible Person, Section 75 ensures clear leadership and accountability. It supports consistent standards, ethical oversight, and open communication with the Council, helping to maintain public trust in anatomical education and research.

Consent Requirements

Before giving consent, a person must receive clear and complete information from the licensed institution so that they can make a fully informed decision about whether to become a donor.

The information provided to a person seeking to donate must include details of:

- The nature of anatomical activities, including the types of teaching and learning activities, and anatomical studies that may occur to donors.
- The user groups who will be undertaking the anatomical activities
- The retention period of the body or body parts
- Any potential loan or transfer of the body (e.g., if the body may be sent to another institution)
- Disposal procedures (cremation, burial, or repatriation)
- Specify the duration for which the body may be used
- The consent may be revoked or amended at any time before death by notifying the licensed institution in writing
- The retention of images following disposal of the donor body for teaching purposes
- Any additional information specified by the Medical Council

The consent must:

- be given in writing using a form specified by the Medical Council
- be given by the person before their death and applies only to anatomical examination.
- be signed and dated in the presence of at least one witness, who also signs to confirm the signature.
- clearly confirm that the donor understands how their body will be used.
- state the length of time for which the body may be used for anatomical examination.
- seek authorisation for images to be taken, including the retention period.
- seek authorisation for loan, and or transfer to another institution.

Anatomical consent is the formal, informed, and voluntary agreement given by a person aged 18 or over to donate their body after death for the purposes of anatomical examination[1]. A licensed institution may only carry out an anatomical examination if it has received valid consent.

[1] Section 63 of the Human Tissue Act 2024.

All licensed institutions must ensure that anatomical examinations are carried out only with fully informed, voluntary, and documented consent. This safeguards the donor's wishes, supports openness and clear communication, and requires careful record-keeping. It also strictly prohibits any financial incentive in connection with donation.

These safeguards are central to protecting dignity, maintaining public trust, and ensuring that the use of human bodies in medical education and research is carried out in line with section 63 of the Act.

Medical Certificate of Cause of Death must be signed before Anatomical Examination can take place

If a person has given consent for their body to be used for anatomical examination after death, the body may be brought to a licensed institution and embalmed or otherwise preserved before the death is formally registered.

No anatomical examination may take place until the licensed institution has received a signed medical certificate confirming the cause of death. This certificate must be completed by a registered medical practitioner. It ensures that the death has been properly certified and that there are no legal or clinical issues that would prevent the body from being used for anatomical purposes.

The licensed institution must keep a copy of the medical certificate for as long as it holds the body or any part of it. After the final disposal of the donor's remains, the certificate must be retained for at least five years, as required under section 64(3) of the Act.

The certificate must be stored securely and made available to the Council or authorised officers if requested.

Keeping this documentation is an important part of the institution's responsibilities. It supports clear record-keeping, traceability, and accountability, and helps ensure transparency in how donated bodies are managed.

By requiring proper certification and secure, long-term record retention, these safeguards protect help maintain public confidence in the anatomical donation process.

Practice of Anatomical Examination

Section 65 sets clear requirements about who can carry out anatomical examinations and where they can take place. Its purpose is to ensure proper oversight, professional standards, and respectful treatment of human remains. Anatomical examinations may only be carried out by:

- The responsible person named on the institution's licence

- A person who is authorised by or working under the direction of the responsible person, provided they are suitably qualified and trained.

This ensures that all examinations are overseen by professionals with the necessary expertise and ethical awareness, and that any duties delegated are carried out safely and appropriately.

Examinations may only take place in a licensed institution. It is a criminal offence to carry out anatomical examinations in any location that is not licensed under Section 68 of the Act.

From the moment a licensed institution accepts a donated body, it is fully responsible for that body until final disposition. Final disposition may include burial, cremation, or returning the remains to the family, in line with the donor's consent. This continuous chain of responsibility ensures that the body is treated with dignity and that all actions are traceable and accountable.

Any person who conducts an anatomical examination outside of a licensed institution, or without proper authorisation, is guilty of an offence. Section 65 ensures that anatomical examinations are carried out only by authorised and qualified individuals within licensed institutions, under strict oversight and ethical standards. By establishing clear boundaries around responsibility, location, and conduct, this section protects the dignity of donors, prevents misuse of human remains, and reinforces public confidence in the integrity of anatomical education and research.

Loan or Transfer of Anatomical Specimens for purposes of Anatomical Examination

Section 66 sets out the requirements for loaning or transferring anatomical specimens between licensed institutions, including institutions in Northern Ireland.

Prior Authorisation Requirement

Anatomical specimens cannot be loaned or transferred without consent of the donor. Donations made prior to the Human Tissue Act 2024 may be loaned or transferred when the donors representative are in support and both institutions agree.

The institution must keep a written record of loan or transfer. This authorisation is essential to:

- Ensure the transfer aligns with the donor's consent.
- Maintain oversight of how specimens are used across institutions.
- Prevent unauthorised or inappropriate use of human remains.

The written record must include:

- Identification of the donor/ specimen(s) to be loaned or transferred.
- The purpose of the loan or transfer.
- The duration of the loan (if applicable).
- Where the specimen will be stored and used.
- Confirmation that the donor's consent permits the transfer or loan, or in historical cases prior the Human Tissue Act 2024 the donors representative is supportive.

The above requirements form the basis of the Transfer Document.

If a donor has already consented to transfer to another licensed institution because the original institution cannot accept the body (for example, due to capacity or facilities), further authorisation from the Medical Council is not required. However, the Council must be notified in advance.

Record-Keeping Requirements
All documents relating to a loan or transfer including consent forms, medical certificates, and transfer records must:

- Accompany the body or specimen to the receiving institution
- Be formally signed out of the lending institution and signed into the receiving institution by the Responsible Person (or a delegated professional)
- Be retained by the lending institution for at least five years after the final disposal of the donor's remains, as required under section 66(7) of the Act.

Records must be stored securely and be available for inspection by authorised officers of the Medical Council.

Responsibility for Specimens
If a specimen is loaned, the **lending institution remains responsible** for the specimen, including ensuring its return and compliance with the donor's consent.

If a specimen is transferred, the receiving institution takes full responsibility, including final disposition in line with the donor's consent.

Section 66 ensures that the transfer or loan of anatomical specimens between licensed institutions is carried out with authorisation from the Council. By requiring prior authorisation, detailed documentation, and clear responsibility for specimens, this section safeguards the dignity of human remains and reinforces accountability across institutions. It supports public trust in the anatomical donation system by ensuring that all specimen movements are lawful, traceable, and aligned with the donor's wishes.

Importation of Anatomical Specimens for Anatomical Examination

Section 67 of the Act governs the importation of anatomical specimens for anatomical examination. Licensed institutions should make every effort to seek donations from within Ireland. However, where this is not possible licensed institutions in Ireland must obtain prior authorisation from the Medical Council in writing before importing anatomical specimens.

The transfer or loan of a donor from Ireland to Northern Ireland would be considered export under the Human Tissue Act 2024. A donor being loaned or transferred from Northern Ireland would be considered as Import under the Human Tissue Act 2024.

Consent Compliance: the specimens must be managed in accordance with any consent given by the donor. The institution must be able to demonstrate that the specimen was obtained, transported, used, and disposed of in line with the donor's consent

Equivalence of Foreign Standards: the Medical Council may require evidence that licenced institution complied with the legal requirements in the country from which the anatomical specimen has been imported.

Records to be kept in relation to Donated Anatomical Specimens

Section 76 outlines that the responsible person at a licensed institution must keep full and accurate records on the management of human specimens used for anatomical examination.

The Responsible Person must maintain a record of all bodies received for anatomical examination. These records may be kept in writing or in another format approved by the Medical Council.

The record must include:

- A copy of the anatomical consent.
- A copy of the medical certificate stating the cause of death.
- Traceability records relating to the storage, use, transportation, disposal or return of an organ, tissue, body, body part or anatomical specimen.

A traceability record is a written log that allows the licensed institution to track exactly what happened to an organ, tissue, body, body part, or anatomical specimen at every stage from the moment it arrives at the licensed institution until its final destination. Section 8 of the Act requires that every action involving these materials must be documented so that there is a complete, reliable chain of information. This ensures that nothing is lost, misidentified, or handled without accountability.

Records must be:

- Secure and permanent.
- Available for inspection by the Medical Council or its authorised officers.

If a specimen is loaned or transferred:

- A copy of the record must accompany the specimen.
- Each receiving institution must retain a copy.
- The original institution must also retain a copy.

The Responsible Person must prepare a written statement outlining policies and procedures to ensure:

- A record management system that protects data and confidentiality.
- An internal audit system with a schedule and accountability.
- Staff are appropriately qualified and trained for their assigned or delegated duties.

Records must be kept in a clear, accessible, and secure format. A copy of the written statement must be available for inspection by the Council or its authorised officers. Failure to maintain proper records may result in regulatory action.

By placing these duties on the designated responsible person, the Act requires that every stage of managing a specimen from its receipt and use to any transfer, importation, or final disposal is properly documented and traceable. Failing to meet these record-keeping obligations can lead to serious regulatory consequences, underscoring how central accurate documentation is to the integrity of anatomical practice.

Section 3: Regulatory Authority and Compliance

Request from the Council for information

This section outlines the authority of the Council to request information from licensed individuals or institutions involved in anatomical examination. The Council may request information from a licence holder. The licenced institution is obliged to provide the requested information within a specified timeframe. This provision ensures transparency, accountability, and regulatory oversight in the use of human bodies for educational and scientific purposes.

Compliance Notices (Anatomical Examinations)

The Council may issue a compliance notice if it believes a person has:

- Contravened provisions of Part 4 of the Act.
- Breached conditions of a licence issued under this Part.
- Contravened codes of practice related to anatomical examination.

Before the Council formally services a compliance notice, they must send an advance notice. The advance notice must be given to the person or institution before a compliance notice is served. The notice must specify the alleged contravention and inform the person of their right to respond or make representations.

Representations: the person has 21 days to respond with representations. The Medical Council must consider the response before making a final decision.

A compliance notice must contain the following information:

- Specify the act or omission that constitutes the contravention.
- Require the person to cease or not commit the act.
- Outline steps to be taken to remedy the issue.
- Require the person to report back within a specified period.
- Request any additional information deemed necessary.

Legal Consequences:

- The notice becomes effective 21 days after service, unless appealed.
- Failure to comply within 21 days of the notice taking effect is an offence.
- Penalties include: a Class C fine; imprisonment up to one year or both.

Appeal of Compliance Notice

Section 83 gives an individual or institution that receives a compliance notice under the Human Tissue Act a formal way to challenge it. It sets out how to appeal the notice to the District Court, and then to the High Court if needed. This appeal pathway provides an opportunity for decisions made by the Medical Council to be reviewed by the courts, supporting fairness, transparency, and accountability in how the regulation of anatomical examinations is carried out.

Appeals

District Court: A person served with a compliance notice may appeal to the District Court within 21 days of receiving the notice. The District Court may:

- Confirm the notice (in whole or in part, with or without amendments). If confirmed, the notice becomes effective 21 days after confirmation, unless further appealed, or on a later date set by the court.
- Allow the appeal, the notice ceases to have effect.

Circuit Court: A person may appeal the District Court's confirmation to the Circuit Court within 21 days. The Circuit Court may:

- Allow the appeal, cancelling the notice.
- Confirm the notice (in whole or in part, with or without amendments) and set the date it takes effect.

High Court: Any party may appeal the Circuit Court's decision to the High Court, **but only on a point of law.** Appeals must be heard by a judge assigned to the district or circuit where the person resides or conducts business.

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