An Roinn Sláinte
Department of Health

Designated Family Member Guidelines

Human Tissue Act 2024 - Part 2 (Transplantation)

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Document Control

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Introduction

The Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024 embeds in legislation the idea that consent is the defining principle across all practices relating to human tissue.

The Minister for Health has prepared and issued these guidelines to give practical guidance for operating and complying with the Act. The following guidelines focus on the concept of consent for the donation of organs, tissues, and cells and the role of the designated family member.

These guidelines have been prepared following consultation with Organ Donation Transplant Ireland, Health Products Regulatory Authority, Intensive Care Society of Ireland, and Irish Blood Transfusion Service, and are intended to be read in conjunction with the relevant provisions of the Human Tissue Act 2024.

DONATION AND TRANSPLANTATION IN IRELAND

The Human Tissue Act provides, for the first time, a national legislative framework for donation and transplantation services in Ireland, for organs, tissues, and cells.

Notably, the Act introduces a soft opt-out system of consent for the donation of relevant organs, that is the liver, lung, pancreas, heart or kidney. This means that when a person dies it is presumed that they would wish to donate their relevant organs after their death, unless they have objected to relevant organ donation.

Under the legislation, those who object to relevant organ donation, for whatever reason, can record their objection on the Relevant Organ Donation Opt-Out Register. The wishes of individuals on the Register will be respected in full, and their family will not be approached on the issue of organ donation.

Regarding those who have not registered their objection on the Relevant Organ Donation Opt-Out Register, it is important to assure people that their family members will always be consulted before any action is taken regarding donation.

The donation of any other organ, tissue, or cell from a deceased person is subject to appropriate consent, which requires the consent of a designated family member.

Purpose

These guidelines give practical guidance regarding the operation of and compliance with the Human Tissue Act 2024 in relation to proposed -

- Removal and transplantation of organs of a relevant person:
    - where deemed consent applies, the seeking of confirmation that there is no objection; or
    - the seeking and obtaining of appropriate consent; as well as
- Removal of tissue and cells from a relevant person, the seeking and obtaining of appropriate consent.

Nothing in these guidelines should be read as placing an obligation on medical professionals to discuss donation with families. Medical professionals are best placed to use their judgement and pursue such conversations where and to the extent appropriate.

Where discussions about organ donation take place, these should be in line with the existing guidance and provisions of the Human Tissue Act 2024.

Review

These guidelines will be reviewed and updated, as required, to ensure that they reflect best practice and remain realistic and balanced.

A review of these guidelines will take place in conjunction with relevant stakeholders within 3 years of commencement of the Act and every 3 years thereafter, or as required.

Key Definitions

Some terms used in these guidelines have a particular meaning under the Human Tissue Act 2024 or other legislation. This means that a word or concept may have a meaning in the context of donation and transplantation which is different than would be understood in ordinary circumstances.

The Glossary towards the end of these guidelines sets out definitions of the terms that have a specific meaning.

An overview of some key definitions relating to the concepts of consent and the designated family member is provided below. This is to give a broad understanding to anyone using these guidelines. These terms and concepts are explained in more detail in the relevant sections of the guidelines or in the Glossary.

Consent

Consent refers to the giving of voluntary or freely given permission for the use of organs, tissues, or cells for the purpose of transplantation activities. The person consenting must have received sufficient information to allow them to understand the nature, risks, and benefits of the donation.

These guidelines will refer to two types of consent – deemed consent and appropriate consent.

DEEMED CONSENT

Deemed consent is where a person's consent for the donation of relevant organs after their death is presumed if –

- the person has not registered an objection on the Relevant Organ Donation Opt-Out Register; and
- the person does not fall within one of the exceptions to deemed consent.

The exceptions to deemed consent are:

- an adult who has not been resident in Ireland for at least 12 months prior to their death.
- an adult who for a significant period prior to their death lacked the capacity to understand that their consent would be deemed if they did not register an objection on the Relevant Organ Donation Opt-Out Register,
- an adult where a designated family member cannot be identified or confirmed,
- a child under 18.

Adults who do not fall within these exceptions may be subject to deemed consent and it will be necessary to check the Relevant Organ Donation Opt-Out Register.

If the person has not registered their objection to organ donation and does not fall within these exceptions, then relevant professionals can approach the person's designated family member to seek confirmation that the person had no objection to organ donation. The designated family member will always be consulted before any action is taken regarding donation.

Where the person has registered their objection on the Relevant Organ Donation Opt-Out Register, their wish will be respected in full. Their family will not be approached about organ donation.

APPROPRIATE CONSENT

Appropriate consent, in these guidelines, refers to consent provided without duress or coercion from the designated family member of the deceased.

In these guidelines, appropriate consent applies in the following situations:

- organ donation where the deceased falls within one of the exceptions to deemed consent,
- donation of organs other than the relevant organs
- donation of tissues and cells.

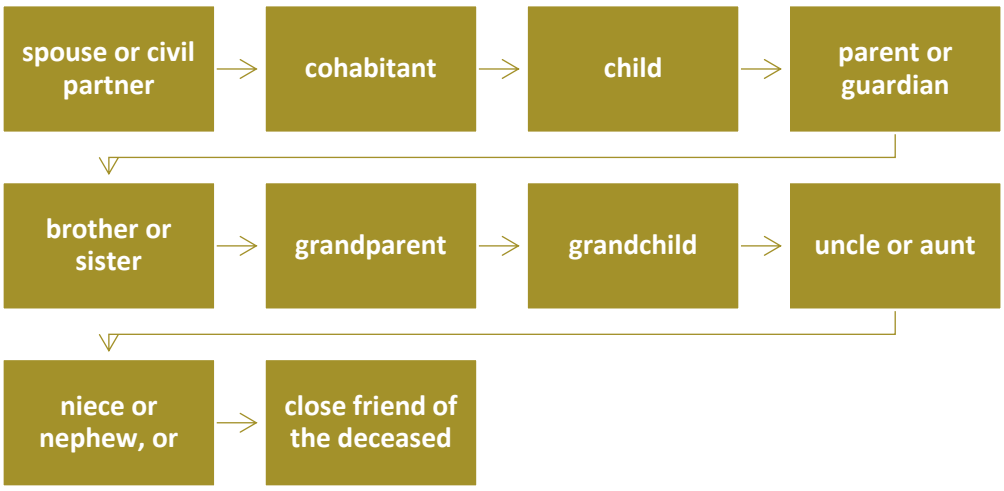
Where appropriate consent applies, donation and transplantation can only proceed with the designated family member's consent.

Appropriate consent can be withdrawn by the designated family member up until the process for the retrieval of the organ, tissue, or cell has started.

Designated Family Member

A designated family member is someone who has an established relationship with the deceased, immediately prior to their death. They will be consulted regarding confirmation of no objection or consent for organ, tissue, or cell donation, as appropriate.

To be a designated family member, the person must have had one of the following relationships with the deceased:



Anyone of the above may be the designated family member if they have had real and substantial contact with the registered medical practitioner regarding the care and treatment of the deceased.

The list also acts as a hierarchy where the standard of contact necessary for real and substantial contact has not been met. In that case, the highest-ranking relationship is spouse or civil partner decreases in order down to close friend.

People may be excluded or disregarded from the hierarchy in line with criteria set out in the Act.

Determining the Designated Family Member

Relevant professionals will look for confirmation of no objection or consent from the designated family member before organ, tissue or cell donation, as appropriate.

The designated family member will be one of the following:

a) spouse or civil partner,
b) cohabitant,
c) child,
d) parent or guardian,
e) brother or sister,
f) grandparent,
g) grandchild,
h) uncle or aunt,
i) niece or nephew, or
j) close friend of the deceased who can demonstrate to the satisfaction of the person seeking consent or confirmation, that he or she can determine and accurately convey the wishes of the deceased.

DISREGARDED PERSONS

People who meet the following criteria will be disregarded as a designated family member.

A disregarded person may not give confirmation of no objection or consent for the purposes of organ, tissue or cell donation.

Persons disregarded for the purposes of determining the designated family member include:

- The deceased's spouse or civil partner if:
    - A deed of separation or a decree of judicial separation (whether granted in Ireland or granted outside the State and recognised in Ireland) has been granted,
    - He or she has entered into a written agreement to separate,

    - He or she has separated and has ceased to cohabit for a continuous period of at least 12 months,
- Persons who do not have the capacity to consent,
- Children under 18 other than when he or she is the parent of the deceased.

EXCLUDED PERSONS

In addition to people disregarded from the list, persons who would otherwise be considered may be excluded from acting as the designated family member if –

- the person
    - does not wish to consider whether he or she objects or consents,
    - is unable to decide whether to object or consent,
    - is unable to confirm that there is no objection to deemed consent,
- it is not reasonably practicable to communicate with the person in the time available if consent in relation to the donation is to be acted on, or
- the relationship between the person and the relevant person cannot be confirmed.

Real and Substantial Contact

Anyone whose relationship with the deceased is described on the list may be determined as the designated family member if they have had real and substantial contact with the registered medical practitioner regarding the care and treatment of the deceased.

The designated family member with whom the registered medical practitioner has had real and substantial contact is referred to as the primary clinical contact.

The primary clinical contact cannot be a person who would be otherwise disregarded or excluded from being a designated family member.

The primary clinical contact, if identified, will be the designated family member approached for confirmation of no objection to the donation or consent. This is regardless of their position on the hierarchy.

Whether or not a primary clinical contact exists will be decided on a case-by-case basis. It is possible that many scenarios will occur where there will have been no real and substantial contact. In those cases, confirmation of no objection or consent should be sought from the person with the highest-ranking relationship on the list.

STANDARD OF CONTACT REQUIRED

It will be for the registered medical practitioner to determine whether there has been real and substantial contact with any designated family member in a given situation.

In order for a person to be identified as having real and substantial contact,

- the person must:
    - have had a relationship with the deceased that falls within one of the relationships described on the list of designated family members; and
    - not be disregarded or excluded from the hierarchy.
- the registered medical practitioner must:
    - have had direct contact with the potential primary clinical contact in relation to the care and treatment of the deceased prior to the death.

A number of other factors may be considered by a registered medical practitioner when assessing whether the direct contact is sufficient to establish real and substantial contact.

- Has the person been present during discussions between the registered medical practitioner and the deceased about care and treatment?
- Has consent for care or treatment been sought or obtained from the person in relation to the care or treatment of the deceased prior to their death?
- Has the person acted in a manner akin to a patient advocate for the deceased prior to their death?
- Is the person listed as “next of kin”?
- Does the person regularly accompany them to medical or hospital appointments or admissions?

If, following consideration of the above, the registered medical practitioner is satisfied that the person meets the standard of real and substantial contact, to be regarded as the primary clinical contact, this should be communicated to the relevant professionals seeking confirmation of no objection or consent, as appropriate.

If, the registered medical practitioner, is not satisfied that real and substantial contact has occurred, confirmation of no objection or consent should be sought from the person with the highest-ranking relationship on the list of designated family members.

Applying the Hierarchy

The list of designated family members acts as a hierarchy where the standard of contact necessary for real and substantial contact has not been met. In that case, the highest-ranking relationship is listed at (a) and decreases in order down to (j).

In some cases, there may be only one person within a given rank of the hierarchy. In which case, they will be the designated family member for the purpose of obtaining confirmation of no objection or consent.

It is possible, that there may be more than one person within a rank of the hierarchy, for example children or siblings. If there are multiple people within the same rank, it is important to note that each person is considered of equal rank and consent may be obtained from any one of them. If a disagreement arises between people of the same rank, then all those within the rank will be asked to reach a consensus agreement.

Role of the Designated Family Member

Once the designated family member has been identified, either by real and substantial contact or the hierarchy, that will be the person approached for confirmation of no objection or consent to donation.

When considering their decision, the designated family member must consider and give substantial weight to whether the deceased would have had an objection to the donation in question.

In reaching a position on this, the designated family member may wish to consider:

- Any conversations they had with the relevant person about their wishes.
- Whether the relevant person carried an organ donor card.
- Whether the relevant person had the 115 code on their driving licence.
- Any other information or knowledge they had which would indicate the preference of the relevant person.

PROCESS OUTLINE A – ORGAN DONATION

The following steps outline the process to determine the applicable consent and the designated family member for the purposes of organ donation.

Please be aware that this process relates to the donation of relevant organs – the liver, lung, pancreas, heart, and kidney. For the donation of any other organ, tissue, or cell please refer to the process outlined in Process Outline B.

Step 1 – Establish if the donation relates to a relevant organ

- If the retrieval and transplantation of one or more of the relevant organs - liver, lung, pancreas, heart, and kidney - is being considered, deemed consent may apply. Proceed to Step 2.
- If retrieval and transplantation relates to any other organ, tissue, or cell, deemed consent does not apply. Please refer to the process outlined in Process Outline B which deals with appropriate consent.

Step 2 - Establish the age of the potential donor

- If the potential donor is over 18, deemed consent may apply. Proceed to Step 3.
- If the potential donor is under 18, deemed consent does not apply. The relevant professional may seek appropriate consent from the parent or guardian. Please refer to the process outlined in Process Outline C which deals with appropriate consent for deceased children.

Step 3 - Is the potential donor an exception to deemed consent?

The exceptions to deemed consent are:

- an adult who has not been resident in Ireland for at least 12 months prior to their death,
- an adult who for a significant period prior to their death lacked the capacity to understand that their consent would be deemed if they did not register an objection on the Relevant Organ Donation Opt-Out Register,
- an adult where a designated family member cannot be identified or confirmed,

– a child under 18.

- If the potential donor meets one or more of the above criteria, deemed consent does not apply. Donation may still be pursued. Please refer to the process outlined in Process Outline B which deals with appropriate consent.
- If the potential donor does not fall within any of above criteria, deemed consent may apply. Proceed to Step 4.

Step 4 – Check the Relevant Organ Donation Opt-Out Register

- If the potential donor recorded an objection on the Relevant Organ Donation Opt-Out Register, then this process will end. The family will not be approached about organ donation.
- If the potential donor has not recorded an objection on the Relevant Organ Donation Opt-Out Register, deemed consent applies. The relevant professional can proceed with determining the designated family member Proceed to Step 5.

Step 5 – Determining the Designated Family Member

The designated family member must be one of the following:

a) spouse or civil partner,
b) cohabitant,
c) child,
d) parent or guardian,
e) brother or sister,
f) grandparent,
g) grandchild,
h) uncle or aunt,
i) niece or nephew, or
j) close friend of the deceased who can demonstrate to the satisfaction of the person seeking consent or confirmation, that he or she can determine and accurately convey the wishes of the deceased.

Step 5a – Disregarded or excluded persons

A disregarded or excluded person may not give confirmation of no objection for the purposes of organ donation.

Disregarded persons include:

- The deceased's spouse or civil partner if:
  - A deed of separation or a decree of judicial separation (whether granted in Ireland or granted outside the State and recognised in Ireland) has been granted,
  - He or she has entered into a written agreement to separate,
  - He or she has separated and has ceased to cohabit for a continuous period of at least 12 months,
- Persons who do not have the capacity to consent,
- Children under 18 other than when he or she is the parent of the deceased.

Excluded persons include:

- Where a person
  - does not wish to consider whether he or she objects or consents,
  - is unable to decide whether to object or consent,
  - is unable to confirm that there is no objection to deemed consent,
- it is not reasonably practicable to communicate with the person in the time available if consent in relation to the donation is to be acted on, or
- the relationship between the person and the relevant person cannot be confirmed.

- If no designated family member remains after this consideration, the process is concluded. Organ donation will not proceed.
- If a potential designated family member remains after this consideration, proceed to Step 5b.

Step 5b - Has there been Real and Substantial Contact

The registered medical practitioner determines if there has been real and substantial contact with any designated family member.

The person must:

- have had a relationship with the deceased that falls within one of the relationships described on the list of designated family members; and
- not be disregarded or excluded from the hierarchy.

The registered medical practitioner must:

- have had direct contact with the potential primary clinical contact in relation to the care and treatment of the deceased prior to the death.

The registered medical practitioner may consider:

- Has the person been present during discussions between the registered medical practitioner and the deceased about care and treatment?
- Has consent for care or treatment been sought or obtained from the person in relation to the care or treatment of the deceased prior to their death?
- Has the person acted in a manner akin to a patient advocate for the deceased prior to their death?
- Is the person listed as "next of kin"?
- Does the person regularly accompany them to medical or hospital appointments or admissions?

- If there has been real and substantial contact, the person who is the primary clinical contact will act as the designated family member. Proceed to Step 6.
- If there has not been real and substantial contact, the hierarchy will determine the designated family member. Proceed to Step 5c.

Step 5c – Applying the hierarchy

The list of designated family member relationships acts as a hierarchy where the standard of contact necessary for real and substantial contact has not been met. In that case, the highest-ranking relationship is spouse or civil partner decreases in order down to close friend.

- Once the highest-ranking relationship is identified, proceed to Step 6.

Step 6 – Seek confirmation of no objection to transplantation activities

If there is more than one person categorised as the designated family member, and

- there is no disagreement, any one member of the rank may or may not provide confirmation of no objection.
- a disagreement arises between people of the same rank, then all those within the rank will be asked to reach a consensus agreement.

The designated family member will be asked whether they will provide confirmation of no objection to transplantation activities involving relevant organs – liver, lung, pancreas, heart, or kidney.

When considering whether or not to confirm that there is no objection to donation regarding deemed consent, the designated family member must consider and give substantial weight to whether the deceased would have had an objection to the donation, removal, transplantation in question. In reaching a position on this, the designated family member may wish to consider:

- Any conversations they had with the relevant person about their wishes;
- Whether the relevant person carried an organ donor card;
- Whether the relevant person had the 115 code on their driving licence;
- Any other information or knowledge they had which would indicate the preference of the relevant person.

- If confirmation of no objection is provided, retrieval, donation and transplantation can proceed.
- If confirmation of no objection is not provided, the process is concluded. Organ donation will not proceed.

Written confirmation of no objection must be obtained in the presence of a witness. Oral confirmation of no objection must be obtained in the presence of two witnesses.

PROCESS OUTLINE B – TISSUE AND CELL DONATION

(including organ donation where deemed consent does not apply)

The following steps outline the process to determine the applicable consent and the designated family member for the purposes of tissue and cell donation.

This process also applies to organ donation where deemed consent does not apply. This includes where the organ being donated is not one of the relevant organs – the liver, lung, pancreas, heart, and kidney. It also may include relevant organ donation by persons who fall into the exceptions to deemed consent.

Step 1 – Confirm that appropriate consent applies

- If the retrieval and transplantation of one or more of the relevant organs - liver, lung, pancreas, heart, and kidney - is being considered, deemed consent may apply. Please refer to the process outlined in Process Outline A which deals with deemed consent.
- If retrieval and transplantation relates to:
    - organ donation where the deceased falls within one of the exceptions to deemed consent,
    - donation of organs other than the relevant organs – the liver, lung, pancreas, heart, or kidney,
    - donation of tissues and cells

  proceed to Step 2.

Step 2 - Establish the age of the potential donor

- If the potential donor is over 18, proceed to Step 3.
- If the potential donor is under 18, the relevant professional may seek appropriate consent from the parent or guardian. Please refer to the process outlined in Process Outline C which deals with appropriate consent for deceased children.

Step 3 – Determining the Designated Family Member

The designated family member must be one of the following:

a) spouse or civil partner,
b) cohabitant,
c) child,
d) parent or guardian,
e) brother or sister,
f) grandparent,
g) grandchild,
h) uncle or aunt,
i) niece or nephew, or
j) close friend of the deceased who can demonstrate to the satisfaction of the person seeking consent or confirmation, that he or she can determine and accurately convey the wishes of the deceased.

Step 3a – Disregarded or excluded persons

A disregarded or excluded person may not give consent for the purposes of donation and transplantation.

Disregarded persons include:

- The deceased's spouse or civil partner if:
  - A deed of separation or a decree of judicial separation (whether granted in Ireland or granted outside the State and recognised in Ireland) has been granted,
  - He or she has entered into a written agreement to separate,
  - He or she has separated and has ceased to cohabit for a continuous period of at least 12 months,
- Persons who do not have the capacity to consent,
- Children under 18 other than when he or she is the parent of the deceased.

Excluded Persons include:

- Where a person
  - does not wish to consider whether he or she objects or consents,
  - is unable to decide whether to object or consent,

        - is unable to confirm that there is no objection to deemed consent,
    - it is not reasonably practicable to communicate with the person in the time available if consent in relation to the donation is to be acted on, or
    - the relationship between the person and the relevant person cannot be confirmed.

- If no designated family member remains after this consideration, the process is concluded. Donation will not proceed.
- If potential designated family members remain after this consideration, proceed to Step 3b

Step 3b - Has there been Real and Substantial Contact

The registered medical practitioner determines if there has been real and substantial contact with any designated family member.

The person must:

- have had a relationship with the deceased that falls within one of the relationships described on the list of designated family members; and
- not be disregarded or excluded from the hierarchy.

The registered medical practitioner must:

- have had direct contact with the potential primary clinical contact in relation to the care and treatment of the deceased prior to the death.

The registered medical practitioner may consider:

- Has the person been present during discussions between the registered medical practitioner and the deceased about care and treatment?
- Has consent for care or treatment been sought or obtained from the person in relation to the care or treatment of the deceased prior to their death?
- Has the person acted in a manner akin to a patient advocate for the deceased prior to their death?
- Is the person listed as “next of kin”?

- Does the person regularly accompany them to medical or hospital appointments or admissions?

- If there has been real and substantial contact, the person who is the primary clinical contact will act as the designated family member. Proceed to Step 4.
- If there has not been real and substantial contact, the hierarchy will determine the designated family member. Proceed to Step 3c.

Step 3c – Applying the hierarchy

The list of designated family member relationships acts as a hierarchy where the standard of contact necessary for real and substantial contact has not been met. In that case, the highest-ranking relationship is spouse or civil partner decreases in order down to close friend.

- Once the highest-ranking relationship is identified, proceed to Step 4.

Step 4 – Seek consent to transplantation activities

If there is more than one person categorised as the designated family member, and

- there is no disagreement, any one member of the rank may or may not provide consent.
- a disagreement arises between people of the same rank, then all those within the rank will be asked to reach a consensus agreement.

The designated family member will be asked whether they will provide consent to transplantation activities.

When considering whether to give appropriate consent, the designated family member must consider and give substantial weight to whether the deceased would have had an objection to the donation, removal, transplantation in question. In reaching a position on this, the designated family member may wish to consider:

- Any conversations they had with the relevant person about their wishes;
- Whether the relevant person carried an organ donor card;
- Whether the relevant person had the 115 code on their driving licence;

- Any other information or knowledge they had which would indicate the preference of the relevant person.

- If consent is provided, retrieval, donation and transplantation can proceed. This is subject to Step 5.
- If consent is not provided, the process is concluded. Donation will not proceed.

Written consent must be obtained in the presence of a witness.
Oral consent must be obtained in the presence of two witnesses.

Step 5 – Withdrawal of appropriate consent

The designated family member can withdraw or amend appropriate consent until the process of removal of organs, tissue, or cells has begun.
Consent cannot be withdrawn once the process of removal of organs, tissue, or cells has begun.

- If consent is withdrawn, prior to the process of removal of organs and tissue and cells beginning, the process is concluded. Donation will not proceed.
- If consent is not withdrawn or withdrawn after the process of retrieval has begun, donation and transplantation can proceed.

Consent by Parent or Guardian in respect of a deceased child for organ, tissue, or cell donation

Deemed consent does not apply to children under 18 years of age. Only a parent or guardian can consent for transplantation activities when children under 18 years of age are the potential donors.

Under the Act, a parent means –

- the father or mother of the child, within the meaning of section 2 of the Guardianship of Infants Act 1964;
- the parent or parents of a donor-conceived child, as defined under section 5 of the Children and Family Relationships Act 2015, or
- the parent that has the sole custody, charge or care of the child.

Consent can be obtained from one parent or guardian for the donation of any organs and tissue and cells, after sufficient information is provided to them so that an informed decision can be taken. This provision extends to parents who are under the age of 18, respecting their rights as parents to make a such an important decision for their child.

The Act makes clear what should happen in cases where one of the parents or guardians consents to the donation, and the other parent or guardian objects to the consent given by the other parent or guardian.

Where an objection is made to a consent, the consent of the first parent or guardian shall be considered invalid if the other parent or guardian objects to the donation before the process of removal has begun. Therefore, if consent is given by one parent or guardian and there is an objection from the other, then donation shall not be pursued.

Appropriate consent for the donation of organs, tissues, or cells can be withdrawn or amended up until the start of the process of retrieval.

PROCESS OUTLINE C – DONATION FROM A DECEASED CHILD

The following steps outline the process to be followed in relation to the donation of organs, tissues, or cells from deceased children.

Step 1 - Establish the age of the potential donor

- If the potential donor is over 18, please refer to the process outlined in Process Outline A (for organ donation of relevant organs) or B (for all other donation of organs, tissues, or cells).
- If the potential donor is under 18, the relevant professional may seek appropriate consent from the parent or guardian. Proceed to Step 2.

Step 2 – Determining the Designated Family Member

Only a parent or guardian can consent for transplantation activities when children under 18 years of age are the potential donors.

Step 3 – Seek consent to transplantation activities

If there is more than one parent or guardian, and

- there is no disagreement, any one parent or guardian may or may not provide consent.
- a disagreement arises between parents or guardians, donation will not proceed.

The parent or guardian will be asked whether they will provide consent to transplantation activities.

- If consent is provided, retrieval, donation and transplantation can proceed. This is subject to Step 4.
- If consent is not provided, the process is concluded. Donation will not proceed.

Written consent must be obtained in the presence of a witness.
Oral consent must be obtained in the presence of two witnesses.

Step 4 – Withdrawal of appropriate consent

A parent or guardian can withdraw or amend appropriate consent until the process of removal of organs, tissue, or cells has begun.

Consent cannot be withdrawn once the process of removal of organs, tissue, or cells has begun.

- If consent is withdrawn, prior to the process of removal of organs and tissue and cells beginning, the process is concluded. Donation will not proceed.
- If consent is not withdrawn or withdrawn after the process of retrieval has begun, donation and transplantation can proceed.

Glossary

This glossary gives an overview of the meaning of certain words and terms which are included in these guidelines. These meanings provide detail and context for some of the terms to assist in understanding their use in the guidelines.

Some of the terms used in these guidelines have been given a particular meaning by the Human Tissue Act 2024 or other legislation. Legislation may give a different meaning to a word or concept than would be understood in ordinary circumstances. These have also been included in the Glossary to aid understanding; however, the Glossary is not intended as a legal interpretation of those terms.

Act

In these guidelines refers the Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024 unless otherwise stated.

Adult

A person of the age 18 and over.

Capacity

A person's decision-making capacity. This will be determined in accordance with section 3 of the Assisted Decision-Making (Capacity) Act 2015.

Cells

Individual human cells or a collection of human cells when not bound by any form of connective tissue.

Child

The term "child" can refer to a person under the age of 18 years of age, or when referring to a designated family member a child of a relevant person.

Civil Partner

A civil partner is either of two persons of the same sex who are parties to a civil partnership registration or to a legal relationship of a class that recognised under Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010 that has not been dissolved or the subject of a decree of nullity.

Cohabitant

One of two adults who live together as a couple in an intimate and committed relationship and who are not married to each other or civil partners of each other.

Consent

The giving of a permission or an agreement, that is voluntarily and freely given or made, for the use of human organs, tissues and cells, for the purpose of transplantation where the person giving consent has received sufficient information to understand the nature, risks, and benefits of the proposed purpose.

Donation

The donation of organs for transplantation or tissues and cells for human application.

Donor

A person who donates organs, tissues, or cells whether that donation takes place during their lifetime or after their death.

Guidelines

This refers to these guidelines unless otherwise specified.

Human Application

The use of tissues or cells on or in a human recipient.

Opt-Out Register

See “Relevant Organ Donation Opt-Out Register”.

Organ

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

Parent

Parent includes, in relation to a:

- child, the father or mother within the meaning of section 2 of the Guardianship of Infants Act 1964 of the child;
- donor-conceived child, the parent or parents of that child under section 5 of the Children and Family Relationships Act 2015, or
- child where one parent has the sole custody, charge or care of the child, that parent.

Primary Clinical Contact

This refers to the designated family member that the registered medical practitioners have had real and substantial contact with regarding the care and treatment of the relevant person.

Registered Medical Practitioner

A person who is a registered medical practitioner within the meaning of section 2 of the Medical Practitioners Act of 2007.

Relevant Organ

A liver, lung, pancreas, heart, or kidney.

Relevant Organ Donation Opt-Out Register

A register maintained by the HSE where adults can register their objections to becoming donors of their relevant organs.

Relevant Professional

In relation to organ transplantation:

- a registered medical practitioner, or
- a suitably qualified person acting on behalf of the registered medical practitioner.

In relation to tissue and cells for human application—

- a registered medical practitioner,
- a suitably qualified person acting on behalf of the registered medical practitioner, or
- a person referred to in Regulation 9(4)(a) of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006;

Sufficient Information

This relates to the confirmation that there is no objection to transplantation activities and the seeking of appropriate consent from the designated family member. The information provided must be:

- clear information sufficient for the designated family member to understand the transplantation activities that are proposed to be carried out including:
    - the purpose and nature of the procurement, its consequences and risks;
    - any analytical tests that may be performed;
    - the recording and protection of donor data;
    - medical confidentiality;
    - the therapeutic purpose and potential benefits of the proposed activities;
    - the applicable safeguards intended to protect the donor (including confidentiality), and
- any information that it would be reasonable, on the request of the donor or designated family member, for the relevant professional to provide to that person in relation to the transplantation activities before or after such activities take place.

Tissue

All constituent parts of the human body formed by cells.

Transplantation

A process intended to restore certain functions of the human body by transferring an organ from a donor to the recipient of the organ.

Transplantation Activities

This can refer to the removal and use of an organ or tissues and cells from the body of a living or deceased person for the purposes of transplantation or human application.