

TITLE

CONSENT TO TREATMENT/PROCEDURE(S): DECEASED DONATION OF HUMAN ORGANS AND TISSUESSCOPE

Provincial

DOCUMENT

PRR-01-05

APPROVAL AUTHORITY

Executive Leadership Team

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SPONSOR

Vice President, Health Professions & Practice;
Associate Chief Medical Officer, Quality & Medical Affairs

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Consent to Treatment/Procedure(s) Policy (#PRR-01)

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January 16, 2023

NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

If you have any questions or comments regarding the information in this document, please contact the Policy & Forms Department at policy@ahs.ca. The Policy & Forms website is the official source of current approved policies, procedures, directives, standards, protocols and guidelines.

OBJECTIVES

- To facilitate an **informed consent process** within Alberta Health Services (AHS) that reflects good practice, contributes to **patient safety**, and promotes compassion for loved ones and families.
- To facilitate a fair, respectful process for **informed consent** that is achieved consistently across all care areas within AHS.
- To facilitate compliance with applicable law.
- This policy will set out the appropriate actions to be taken during the informed consent process for human organ and tissue donation.

PRINCIPLES

The principle of respect for persons reflects the importance of patients and families being able to determine what happens in situations where donations of human organs and tissues have been expressed by either the patient or their family. In keeping with the patient's values and beliefs, where patients cannot make their own decisions, respect for persons is upheld by recognizing the decision-making role of an appropriate **alternate decision-maker**.

Informed consent:

- requires **capacity**;
- shall be informed;

- shall be specific;
- shall be voluntary;
- requires understanding; and
- shall be documented.

The **most responsible health practitioner (MRHP)** providing the **treatment/procedure(s)** has a duty to offer the option and opportunity for human tissue and organ donation. Informed consent for human tissue and organ donation shall be obtained by the relevant **donation organization**.

AHS is committed to providing continuing education for all personnel to implement this policy and the subsequent procedures.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Accountability

- 1.1 The accountability to obtain informed consent for organ and/or tissue donation shall rest with the donation organization that was notified that a person's tissue or organs may be suitable for transplantation. Informed consent may be obtained by a **health care provider** trained in organ and tissue donation screening and in the donation and procurement consent process. The relevant donation organization shall make the determination of who is eligible to obtain consent in each location.
 - a) If the **consenter** is having difficulty understanding the discussion or reading and completing the **consent form**, the discussion and contents of the consent form shall be read and explained to the consenter in the presence of a witness and with the assistance of an interpreter, as necessary. Documentation of this process is required.
- 1.2 If the Medical Examiner is involved, the Medical Examiner shall be notified and permission to proceed shall be obtained by the donation organization. The Medical Examiner may release any and all records and reports pertaining to **donor** information to the donation organization.

2. Who May Give Informed Consent (Deceased Donor)

- 2.1 A deceased person's tissues or organs may be donated for transplant, medical education, or scientific research if informed consent was given by:

- a) the **adult** patient prior to their death; or
 - b) if the adult has died prior to giving informed consent or their death is imminent and the person is incapable of consenting by reason of injury or disease, or the person was a **minor**, then a person in one (1) of the following groups and in the following order of priority, may provide informed consent:
 - (i) the spouse or **adult interdependent partner** of the donor if they are not **estranged**;
 - (ii) an adult child of the donor;
 - (iii) a parent or **guardian** of the donor;
 - (iv) an adult sibling of the donor; or
 - (v) any other adult next of kin of the donor.
- 2.2 Informed consent shall not be sought from a person listed in Section 2.1b) above, if there is knowledge that:
- a) the donor would have refused to give informed consent;
 - b) a person in a higher priority group is readily available to provide informed consent; or
 - c) a person in the same group would refuse to give informed consent.

3. Written Informed Consent is Required

- 3.1 The informed consent for tissue or organ donation shall be in writing, dated and signed by:
- a) the consenter and a witness. The relevant donation organization shall make the determination of who is eligible to obtain informed consent in each location; or
 - b) two (2) witnesses of the consenter's agreement upon the instruction of the consenter, if the consenter cannot sign for any reason (e.g., telephone consent). One (1) of the witnesses shall be knowledgeable in the donation process and has advised the consenter of the nature and consequences of donation. The manner in which the consenter's agreement was obtained shall be evidenced on the consent form.
- 3.2 When the consenter cannot be present to provide a signature, informed consent may be obtained by telephone, facsimile, or electronically in compliance with Section 3.1 above. The identity of the consenter shall be verbally confirmed, with no further proof of identity required.

- 3.3 The following persons shall not witness informed consent:
- a) the Physician who will remove the tissue or organ or perform the transplantation;
 - b) the recipient of the transplant and their immediate family; or
 - c) the consenter for the donation.
- 3.4 The written consent shall contain:
- a) the name of the donor;
 - b) the name, address, and telephone number of the consenter, and their relationship to the donor;
 - c) an explanation that the organs and tissues are a gift, and that neither the donor's estate nor will the consenter receive any reward, benefit, monetary compensation, or valuable consideration for it;
 - d) a description of the general types of organs and tissues to be recovered;
 - e) a description of the permitted use(s) of the recovered organs and tissues (i.e., transplant, scientific research previously approved by a research ethics review committee, medical education);
 - f) an explanation that recovery of organs and tissues requires the following actions, and the informed consent specifically authorizes:
 - (i) access to, and required disclosure of, the donor's medical and other relevant records;
 - (ii) testing and reporting for transmissible diseases;
 - (iii) the removal of specimens which may include, but are not limited to, the spleen, lymph nodes, and blood samples, for the purpose of determining suitability and/or compatibility of donor and recipient;
 - (iv) the release to the donation organization of any and all records, and reports of a Medical Examiner or Pathologist; and
 - (v) such other requirements as may be applicable for the donation process, such as transport of body, archiving of samples, etc.;
 - g) information that the consenter was advised of the nature and consequences of donation; and
 - h) any special family requests.

- 3.5 Patient consent for organ and tissue donation that is documented on the patient's Alberta Personal Health Card shall be considered valid, even if it is undated.
- 3.6 Patient consent for organ and tissue donation that is documented within the Alberta Organ Donation Registry shall be considered valid, even though it is not witnessed.

Attention: If it is known that the donor had previously indicated their wishes on any other Provincial/State Registry, there shall be a discussion with the patient's family.

- 3.7 Where a family member disagrees with the patient's wish to donate organs or tissue and where the patient's consent for organ and tissue donation is documented on their Alberta Personal Health Card or the Alberta Organ Donation Registry, an emergency ethics and legal consultation should be requested through the senior administrator on-call.

4. Providing Relevant Information

- 4.1 The consenter shall be informed of the nature and consequences of donating tissue and/or organs for the purpose of implanting into another person, or for medical education and/or scientific research.
- 4.2 The informed consent discussion is a shared process between the consenter and the donation organization, resulting in the consenter's decision to accept or refuse the proposed donation.
- 4.3 Information shall be provided in a manner that is understandable by the consenter. If appropriate, the consenter should indicate that they understand the meaning of neurologic death or donation after cardio-circulatory death.
- a) The donation organization shall communicate in a manner that supports the consenter's ability to understand and shall address all communication barriers including, but not limited to:
- (i) hearing;
 - (ii) sight;
 - (iii) language;
 - (iv) culture;
 - (v) literacy;
 - (vi) level of education;
 - (vii) level of anxiety and stress; and

(viii) environmental factors, including location of discussion.

4.4 The consentor shall be informed of the following by the individual obtaining informed consent:

- a) the donated tissue and/or organs are considered by AHS as a gift(s) and neither the donor nor the consentor will receive any reward, benefit, or valuable consideration for the gift;
- b) the donation process, including archiving of samples and contact information for the donation organization(s);
- c) donor relocation, if applicable;
- d) the specific types of tissues and/or organs that may be recovered;
- e) the general purposes for which the tissues and/or organs will be used;
- f) organs and tissues are recovered utilizing standard procedures that maintain the respect and dignity of the donor;
- g) the donor is reconstructed after the tissues and/or organs are recovered so the disfiguration is minimized;
- h) if the tissues and/or organs are for transplantation to another individual, blood, spleen, lymph nodes, and/or tissue samples shall undergo diagnostic testing to determine that they are healthy and suitable and/or compatible for donation;
- i) a blood sample from the donor, and the donor's birth mother if 18 months old or less or who has been breastfed in the last 12 months, shall be tested for transmissible diseases including, but not limited to:
 - (i) hepatitis B;
 - (ii) hepatitis C;
 - (iii) human T-lymphotropic virus type I and II;
 - (iv) syphilis; and
 - (v) human immunodeficiency virus type 1 and 2.

Evidence of active infection shall be provided to the donor's Physician and/or the Medical Officer of Health as required under the *Public Health Act*. If there is evidence of active infection, the tissues and/or organs may not be suitable for transplantation;

- j) sharing and disclosure of information from the donor's **health record** is required to assess donor suitability, to obtain the donation, and to assess medical suitability of the tissue and/or organs for transplantation (this information may be stored electronically; information may be shared nationally or internationally in compliance with the *AHS Collection, Access, Use, and Disclosure of Information Policy* and the *AHS Privacy Protection and Information Access Policy*); and
- k) there is a possibility that the donor's tissues and/or organs may be sent out of the city, province, and/or country.

5. Withdrawal of Informed Consent

- 5.1 Informed consent to tissue and/or organ donation may be withdrawn in accordance with the hierarchy outlined in Section 2.1 above.
- 5.2 Withdrawal of informed consent may be done at any time during the donation process.
- 5.3 Upon a withdrawal of informed consent, the donation organization shall stop the donation process and revisit the informed consent process. The consentor may provide informed consent again at any time following an informed consent discussion.
- 5.4 Withdrawal of informed consent shall be documented on the *AHS Tissue and/or Organ Donation Consent (Human Tissue and Organ Donation Act of Alberta)* Form and shall meet the requirements set out in Section 3.1 above.
- 5.5 In the event that withdrawal of informed consent is not documented on the consent form, it shall be documented in the **donor record** and shall include the name and relationship of the individual withdrawing informed consent.

6. Documentation

- 6.1 The person obtaining informed consent is accountable for ensuring appropriate documentation of the informed consent process and outcomes on the donor record.
- 6.2 A copy of the consent form shall be maintained in the donor record.

DEFINITIONS

Adult means a person aged 18 years and older.

Adult interdependent partner means two adults who have lived in a relationship of interdependence

- a) for a continuous period of not less than three (3) years;
- b) with some permanence if there is a child of the relationship by birth or adoption; or
- c) there exists an interdependent partner agreement between the two.

Agent means the person(s) named in a personal directive who can make decisions on personal matters according to the wishes expressed by the patient.

Alternate decision-maker means a person who is authorized to make decisions with or on behalf of the patient. These may include, specific decision-maker, a minor's legal representative, a guardian, a 'nearest relative' in accordance with the *Mental Health Act* (Alberta) or an agent in accordance with a Personal Directive or a person designated in accordance with the *Human Tissue and Organ Donation Act* (Alberta). This also includes what was previously known as the substitute decision-maker.

Capacity means the ability for the patient to 1) understand the nature, risks, and benefits of the procedure and the consequences of consenting or refusing; and 2) understand that this explanation applies to them.

Consenter means the individual giving the consent.

Consent form means, for the purposes of this policy, an Alberta Health Services approved form of documentation that can be used to provide evidence of the outcome of the consent to human organ and tissue donation process.

Donation organization means the following Alberta Health Services programs designated as donation agencies pursuant to the *Human Tissue and Organ Donation Regulation*:

- a) Comprehensive Tissue Centre;
- b) Human Organ Procurement and Exchange North Program; and
- c) Southern Alberta Organ and Tissue Donation Program.

Donor means a deceased individual whose body is the source of the organ and tissue.

Donor record means a separate Alberta Health Services record, created once consent is obtained for human tissue and organ donation. All documents related to the donation are maintained in this record and identified with a unique donor identifier as required, to maintain confidentiality of the donor.

Estranged means living separately and apart for a year or more.

Guardian means, where applicable:

For a minor:

- a) A guardian as defined by the *Family Law Act* (Alberta), a divorced parent with custody of the minor, or a person appointed pursuant to a will, personal directive, court order, agreement or by authorization of legislation (e.g., *Child, Youth and Family Enhancement Act* [Alberta]).

For an adult:

- a) An individual appointed by the Court in accordance with the *Adult Guardianship and Trusteeship Act* (Alberta) to make decisions on behalf of the adult patient when the adult patient lacks capacity.

Health care provider means any person who provides goods or services to a patient, inclusive of health care professionals, staff, students, volunteers, and other persons acting on behalf of or in conjunction with Alberta Health Services.

Health record means the collection of all records documenting individually identifying health information in relation to a single person.

Informed consent means the patient's agreement (or alternate decision-maker) to undergo a treatment/procedure after being provided, in a manner the patient can understand, with the relevant information about the nature of the treatment/procedure(s), its benefits, potential risks and alternatives, and the potential consequences of refusal.

Informed consent process means a discussion or series of discussions and interactions that may occur over a period of time between the most responsible health practitioner and patient or their alternate decision-maker (if applicable) including: i) the determination of capacity, as necessary, ii) the provision of relevant information, iii) the verification of understanding, iv) the decision-making and v) documentation of the consent process and outcome.

Minor means a person aged less than 18 years.

Most responsible health practitioner (MRHP) means the health practitioner who has responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by Alberta Health Services to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

Patient means all persons, inclusive of residents and clients, who receive or have requested health care or services from Alberta Health Services and its health care providers. Patient also means, where applicable:

- a) a co-decision-maker with the person; or
- b) an alternate decision-maker on behalf of the person.

Personal directive means a written document in accordance with the requirements of the *Personal Directives Act* (Alberta), in which an adult names an agent(s) or provides instruction regarding their personal decisions, including the provision, refusal, and/or withdrawal of consent to treatments/procedures. A personal directive (or part of) has effect with respect to a personal matter only when the maker lacks capacity with respect to that matter.

Treatment/procedure(s) means a specific assessment, treatment, investigative procedure(s), or series of treatments/procedures planned to manage a clinical condition; these can be presented as a treatment plan/intervention.

REFERENCES

- Alberta Health Services Governance Documents:
 - *Collection, Access, Use, and Disclosure of Information Policy* (#1112)
 - *Consent to Mental Health Treatment/Procedure(s): Formal Patients and Persons Subject to Community Treatment Orders Under the Mental Health Act Policy* (#PRR-01-04)
 - *Consent to Treatment/Procedure(s) Policy* (#PRR-01)
 - *Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity Procedure* (#PRR-01-02)
 - *Consent to Treatment/Procedure(s): Minors / Mature Minors Procedure* (#PRR-01-03)
 - *Information Technology Acceptable Use Policy* (#1109)
 - *Privacy Protection and Information Access Policy* (#1177)
 - *Transmission of Information by Facsimile or Electronic Mail Policy* (#1113)
- Alberta Health Services Forms:
 - *Consent to Treatment Plan/Intervention or Procedure Form* (#09741)
 - *Tissue and/or Organ Donation Consent (Human Tissue and Organ Donation Act of Alberta) Form* (#09816)
- Non-Alberta Health Services Documents:
 - *Adult Guardianship and Trusteeship Act* (Alberta)
 - *Adult Interdependent Relationships Act* (Alberta)
 - *Child, Youth and Family Enhancement Act* (Alberta)
 - *Family Law Act* (Alberta)
 - *Health Information Act* (Alberta)
 - *Human Tissue and Organ Donation Act* (Alberta)
 - *Human Tissue and Organ Donor Regulation* (Alberta)
 - *Personal Directives Act* (Alberta)
 - *Public Health Act* (Alberta)

VERSION HISTORY

Date	Action Taken
February 27, 2012	Non-substantive change
October 30, 2012	Revised
November 6, 2012	Non-substantive change
January 16, 2020	Revised, includes change in Title from <i>Consent to Treatment: Human Tissue and Organ Donation</i> and change in document type from Procedure