CONSENT TO TREATMENT: HUMAN TISSUE AND ORGAN DONATION

OBJECTIVES
This procedure will set out the appropriate actions to be taken during the consent process for human tissue and organ donation.

This procedure will address:

1. Who may give consent (deceased donor)
2. Who may give consent (living donor)
3. Written consent is required
4. Accountability
5. Providing relevant information
6. Withdrawal of consent
7. Documentation

APPLICABILITY
Compliance with this procedure 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). This procedure does not limit any legal rights to which you may otherwise be entitled.
PROCEDURE

1. Who May Give Consent (Deceased Donor)

1.1 A person’s tissues or organs may be donated for transplant, medical education or scientific research from his or her deceased body if informed consent was given by

a) the adult donor prior to his or her death, or

b) if the adult died prior to giving consent, or the person was a minor, then a person in one of the following classes and in the following order of priority, may provide consent:

1. the spouse or adult interdependent partner of the donor if they are not estranged;

2. an adult child of the donor;

3. a parent or guardian of the donor;

4. an adult sibling of the donor; or

5. any other adult next of kin of the donor.

1.2 Consent shall not be sought if:

a) the donor would have refused to give consent;

b) a person in a higher priority class is readily available to provide consent; or

c) a person in the same class would refuse to give consent.

2. Who May Give Consent (Living Donor)

2.1 A living adult’s tissue or organs may be donated for transplantation if the adult gives informed consent or, in circumstances where the adult lacks capacity to consent,

a) by an agent under the Personal Directives Act, where the Personal Directive authorizes the agent to provide such a consent; or

b) by a guardian for the adult under the Adult Guardianship and Trusteeship Act where a court order authorizes the guardian for the adult to provide such a consent.

2.2 If death is imminent, and the adult has not given consent and, in the opinion of a physician is incapable of doing so by reason of injury or disease, or if the person is a minor, informed consent may be obtained in accordance with 1.1 (b) and 1.2 of this procedure.
2.3 A living minor’s tissues or organs may be donated for transplant:
   a) if the guardian for the minor gives informed consent, and there is no knowledge that another guardian for the minor would refuse or that the consenting guardian for the minor lacks authority to make a medical decision; and
   b) the Independent Assessment Committee has approved the transplant.

   **Note:** Only regenerative tissue or organs may be donated if the minor is under 16 years of age.

2.4 A living minor’s tissue or organ that is a waste product of a medical procedure may be donated for transplant if informed consent is provided by a guardian for the minor or by the minor, if the minor is 16 years of age or over or lives independently of a guardian for the minor.

3. **Written Consent is Required**

3.1 The consent for tissue or organ donation must be in writing, dated and signed by:
   a) the consenter and two persons who witnessed the consent. One of the witnesses must be knowledgeable in the donation process and has advised the consenter of the nature and consequences of donation; this individual obtaining consent is considered to be the first witness.
   b) two witnesses upon the instruction of the consenter, if the consenter cannot sign for any reason. One of the witnesses must be knowledgeable in the donation process and has advised the consenter of the nature and consequences of donation.

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 3.1.

3.3 The following persons shall not witness a consent:
   a) the physician who will remove the tissue or organ or perform the transplantation;
   b) the recipient of the transplant and his or her immediate family;
   c) a person who is required to give a consent in respect of the same donation.

3.4 The written consent must contain:
   a) the name of the donor;
   b) the name, address, and telephone number of the consenter, and his/her relationship to the donor;
c) an explanation that the organs and tissue are a gift, and that neither the donor's estate nor the consenter will receive any reward, benefit, monetary compensation or valuable consideration for it;

d) a description of the general types of organ/ tissue to be recovered;

e) a description of the permitted use(s) of the recovered organ/ tissues (i.e. transplant, therapy, research, or education; when consent for research is obtained, the study must have been approved by a research ethics review committee);

f) an explanation that recovery of organ/tissue requires the following actions, and the consent specifically authorizes:

- access to, and required disclosure of, the donor’s medical and other relevant records;
- testing and reporting for transmissible diseases;
- 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;
- the release to the donation agency/tissue bank of any and all records and reports of a Medical Examiner, Coroner or Pathologist; and,
- such other requirements as may be applicable for the specific donation or tissue bank, such as transport of body, archiving of samples, etc.

g) contact information for the donation agency represented by the person obtaining the consent;

h) information that the consenter was advised of the nature and consequences of donation;

i) any special family requests.

### 3.5

A consent on the form provided on a certificate of registration issued under the *Health Insurance Premiums Act* (Alberta Personal Health Card), is valid, even if it is undated.

a) In the event that a family member opposes a consent for donation, on a person's certificate of registration issued under the *Health Insurance Premiums Act*, an emergency ethics consultation should be requested through the senior administrator on-call.
4. Accountability

4.1 The accountability to obtain informed consent for tissue and/or organ donation shall rest with the donation agency that was notified a person’s tissue or organs may be suitable for transplantation. In certain circumstances informed consent may be obtained by a health care provider trained in tissue and organ donation screening and in the donation and procurement consent process.

Note: If the donor is a Medical Examiner’s case, the Medical Examiner must be notified and permission to proceed must be obtained. The Medical Examiner may release any and all records and reports pertaining to donor information to the donation agency(-ies).

5. Providing Relevant Information

5.1 The individual providing informed consent 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. If appropriate, the consenter shall indicate that they understand the meaning of neurologic brain death or donation after cardiac death. The consenter shall be informed of the following by the individual obtaining informed consent:

a) the donated tissue and/or organs are considered by Alberta Health Services as a gift(s) and neither the donor nor the consenter will receive any reward, benefit or valuable consideration for the gift;

b) the donation process, including archiving of samples, contact information for the donation agency(ies);

c) donor relocation, if applicable;

d) the specific types of tissues and/or organs that may be recovered;

e) the general purpose for which the retrieved tissues and/or organs will be used;

f) tissues and organs are recovered utilizing standard recovery 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 will undergo diagnostic testing to ensure 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, will be tested for transmissible diseases including, but not limited to:
• Hepatitis B and C
• Human T-Lymphotropic Virus type I and II
• Syphilis
• Human Immunodeficiency Virus type 1 and 2

Positive results will be provided to the donor’s physician and/or Medical Officer of Health as required under the Public Health Act. If there are positive results, 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 Alberta Health Services Protection and Privacy of Health and Personal Information 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.

6. Withdrawal of Consent

6.1 Upon the withdrawal of consent to tissue and/or organ donation, the consenter must provide a withdrawal of consent that is in writing, dated and signed by the consenter and a witness or if a consenter cannot sign for any reason, by two (2) persons who witnessed the withdrawal of consent.

6.2 The consenter is required to provide copies of the withdrawal of consent to persons who have copies of the consent.

7. Documentation

7.1 The person obtaining informed consent is accountable for ensuring appropriate documentation of the consent process and outcomes on the donor record.

7.2 The original consent form must be maintained in the donor record.

DEFINITIONS

Adult means a person aged eighteen (18) years and older.

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 or an agent in accordance with a personal directive or a person designated in accordance with the Human Tissue and Organ Donation Act.

Capacity means 1) the patient understands the nature, risks and benefits of the procedure and the consequences of consenting or refusing and 2) the patient understands that this explanation applies to him/her.

In the context of treatment of a formal patient or a person subject to a Community Treatment Order under applicable mental health legislation, capacity is addressed in section 26 of the Mental Health Act which states that a person is mentally competent to make treatment decisions if the person is able to understand the subject matter relating to the decisions and able to appreciate the consequences of making the decisions.

Consenter means the individual giving the consent.

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

Donation agency 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; and
   c) Southern Alberta Organ and Tissue Donation Program.

Donor means a living or deceased individual whose body is the source of the organ/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) as defined in the Family Law Act see Appendix A;
   b) as per agreement or appointment authorized by legislation (obtain copy of agreement and verify qualifies under legislation) (e.g., agreement between a Director of Child and Family Services Authority and foster parent(s) under the Child, Youth and Family Enhancement Act; or agreement between parents under the Family Law Act; or as set out in Child Youth and Family Enhancement Act regarding guardians of the child to be adopted once the designated form is signed);
   c) as appointed under a will (obtain copy of will; also obtain Grant of Probate, if possible);
d) as appointed in accordance with a personal directive (obtain copy of personal
directive);
e) as appointed by court order (obtain copy of court order) (e.g., order pursuant to
Child, Youth and Family Enhancement Act); and
f) a divorced parent who has custody of the minor.

For an adult:
a) an individual appointed by the Court to make decisions on behalf of the adult patient
when the adult patient lacks capacity.

Health care provider means any person acting on behalf of Alberta Health Services who is
providing a good or a service 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 Alberta Health Services legal record of the patient's diagnostic,
treatment and care information.

Independent Assessment Committee means a committee established for the purposes of
approving a donation by a minor in compliance with the Human Tissue and Organ Donor
Regulation.

Informed consent means the agreement of a patient to the patient undergoing a
treatment/procedure after being provided with the relevant information about the
treatment/procedure(s), its risks and alternatives and the consequences of refusal.

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.

Living donor means an individual who consents to the recovery or collection of his or her
organ/tissue, where recovery or collection is to take place while she or he is alive.

Minor means a person aged less than eighteen (18) years.

Patient means all persons who receive or have requested health care or services from Alberta
Health Services and its health care providers and 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 in which an adult names an agent(s) or provides instruction regarding
his/her personal decisions, including the provision, refusal and/or withdrawal of consent to
treatments/procedure(s). 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 means a specific treatment, investigative procedure(s), or series of
treatments/procedures planned to manage a clinical condition.
REFERENCES

Appendices
- Appendix A  Overview of the Definition of “Guardian” as Set Out in Section 20 of the Family Law Act

Alberta Health Services Policies and Procedures
- Alberta Health Services Policy: Consent to Treatment/Procedure(s)
- Alberta Health Services Procedure: Consent to Treatment/Procedure(s): Adults with Capacity
- Alberta Health Services Procedure: Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity
- Alberta Health Services Procedure: Consent to Treatment/Procedure(s): Minors/Mature
- Alberta Health Services Procedure: Consent to Treatment/Procedure(s): Formal Patients and Persons Subject to Community Treatment Orders under the Mental Health Act
- Alberta Health Services Policy: Information Technology Acceptable Use
- Alberta Health Services Policy: Transmission of Information by Facsimile or Electronic Mail
- Alberta Health Services Policy: Alberta Health Services Protection and Privacy of Health and Personal Information

Alberta Health Services Forms
- Consent to Specific Treatment/Procedure (#09741)
- Consent to Human Tissue and/or Organ Donation (#09816)

Legislation
- 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)

REVISIONS
October 31 2012
Overview of the Definition of “Guardian” as Set Out in Section 20 of the *Family Law Act*

A guardian is a parent if:

1. the parent has acknowledged that he or she is the parent of the child; AND
2. has demonstrated an intention *(see guidelines below)* to assume the responsibility of a guardian in respect of the child within one year of either becoming aware of the pregnancy or becoming aware of the birth.

*Parentage (who is a parent):*

There are three combinations of parent-child relationships recognized under the *Family Law Act:*

<table>
<thead>
<tr>
<th>Children conceived without assisted reproduction:</th>
<th>Children conceived with assisted reproduction and whose birth mother is the intended parent:</th>
<th>Children who were conceived with assisted reproduction and whose birth mother is a surrogate:</th>
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<tbody>
<tr>
<td>Birth mother and biological father are the parents, except in the case of adoption where one would refer to the adoption Court Order. If adoption is in progress, contact Clinical Legal Services.</td>
<td>The birth mother will be considered to be one parent.</td>
<td>Until there is a Court Order declaring parentage, the surrogate remains the <strong>only</strong> legal parent.</td>
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<td><em>see below for who is presumed to be the biological father.</em></td>
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<td>The other parent will depend on how the embryo was created:</td>
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<td>1. If the embryo was created from the intended male parent’s sperm, then the other legal parent is the intended male parent.</td>
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<td>2. If the embryo was created from donated sperm, then the person who was</td>
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<td>Once the surrogate has relinquished her parental rights, a Court Order will declare the proper legal parents.</td>
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</table>
**CONSENT TO TREATMENT: HUMAN TISSUE AND ORGAN DONATION**

**INTENTION TO ASSUME RESPONSIBILITY**

*May be shown by any of the following:*

1. Being married to the other parent at the time of the birth of the child;
2. Being married to the other parent after the birth of the child;
3. Being married to the other parent that, within 300 days before the birth of the child ended by death, decree of nullity or judgment of divorce;
4. Being an adult interdependent partner of the other parent at the time of birth of the child;
5. Being an adult interdependent partner with the other parent after the birth of the child;
6. Having cohabited with the other parent for at least 12 consecutive months during which time the child was born;
7. Having entered into an agreement with the other parent to be a guardian under the *Family Law Act*;
8. Having carried the pregnancy to term (for the birth mother);
9. Where the other parent is the birth mother, voluntarily providing or offering to provide support for the birth mother during or after her pregnancy, not by court order;
10. Voluntarily providing or offering to provide reasonable direct or indirect financial support for the child;
11. Court Order (a Court may find other evidence that demonstrates a parent’s intention to assume the responsibility of a guardian in respect of the child);
12. Where the child is born as a result of assisted reproduction, being a parent of the child under section 8.1 (see middle column under Parentage above).
BIOLOGICAL FATHER
The following will be presumed to be the biological father where the child was born without assisted reproduction (see first column under Parentage above):

The male person who:

1. Was married to the birth mother at the time of the child’s birth;
2. Was married to the birth mother by a marriage that within 300 days before the birth of the child ended by: death; decree of nullity; or judgment of divorce;
3. Married to the birth mother after the child’s birth and has acknowledged that he is the father;
4. Cohabitated with the birth mother for at least 12 consecutive months during which time the child was born and he has acknowledged that he is the father;
5. Cohabitated with the birth mother for at least 12 consecutive months and the period of cohabitation ended less than 300 days before the birth of the child;
6. Is registered as the parent of the child at the joint request of himself and the birth mother under the Vital Statistics Act, or under similar legislation in a province or territory other than Alberta;
7. Has been found by a Court of competent jurisdiction in Canada to be the father of the child for any purpose.

Note: Two people cannot be presumed to be the biological father. If that is the case, then no one will be presumed to be the biological father.