



TITLE

CONSENT TO TREATMENT/PROCEDURE(S)

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Patient Rights and Responsibilities

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If you have any questions or comments regarding the information in this policy, please contact the Clinical Policy Department at clinicalpolicy@albertahealthservices.ca. The Clinical Policy website is the official source of current approved clinical policies, procedures and directives.

PURPOSE

- To facilitate a Consent Process within Alberta Health Services that reflects good practice, contributes to Patient safety, and enhances the Patient experience.
- To facilitate a fair, respectful and informed Consent Process that is achieved consistently.
- To facilitate compliance with applicable legislation.

POLICY STATEMENT

- Patients have the right to be informed about the benefits and risks of any Treatment/Procedure offered to them, and to make a voluntary decision (with certain exceptions under the *Mental Health Act*) about whether to undergo the Treatment/Procedure.
- The principle of respect for persons reflects the importance of Patients being able to determine what happens to their own bodies, in keeping with their own 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.
- The Most Responsible Health Practitioner providing a Treatment/Procedure to a Patient has a duty to inform the Patient of the nature of the Treatment/Procedure, its risks and benefits, alternatives, and consequences. Advice about risks and benefits should be as specific to the Patient as available knowledge and information will allow.
- Information should be conveyed accurately and in a manner that the Patient can understand. Consent must be obtained without coercion or undue influence from any Health Practitioner or third party.
- Informed Consent may be expressed verbally, or in writing, or be implied.
- Informed Consent should be a process between the Patient and the Most Responsible Health Practitioner. Information may be discussed over a period of time, culminating in the

Patient's decision to accept or refuse the Treatment/Procedure. A written Consent Form when required is evidence of the Patient's agreement for the Patient to undergo a Treatment/Procedure and should only be signed once the Patient has had time to reflect, ask questions, understand and reach an informed, voluntary decision (with certain exceptions under the *Mental Health Act*).

APPLICABILITY

Compliance with this policy is required by all AHS employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of AHS (including contracted services providers as necessary). This policy does not limit any legal rights to which you may otherwise be entitled.

POLICY ELEMENTS

1. Consent is required

1.1 Before a Treatment or Procedure is provided, there must be Express or Implied Consent, unless a valid exception applies. See the following Alberta Health Services procedures for details of valid exceptions:

- Consent to Treatment/Procedure(s): Adults with Capacity
- Consent to Treatment/Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity
- Consent to Treatment/Procedure(s): Minors/Mature Minors
- Consent to Treatment/Procedure(s): Human Tissue and Organ Donation
- Consent to Treatment/Procedure(s): Formal Patients and Persons Subject to Community Treatment Orders under the *Mental Health Act*.

a) Additional Treatment/Procedure(s) that have nothing to do with the original Treatment/Procedure(s) but are discovered to be convenient at the time, or even beneficial, may not be performed without prior consent except in the case of an emergency.

1.2 All consent shall be informed whether it is Express or Implied Consent.

1.3 The Most Responsible Health Practitioner is responsible for ensuring that there is valid and informed consent for any given Treatment/Procedure(s) and is also responsible for determining the most appropriate method of obtaining that consent. Informed Consent may be expressed verbally or in writing, or be implied.

Notwithstanding section 1.3, and with the exception of an emergency situation (in an emergency, please refer to the applicable consent procedure) Express written consent shall be obtained for the transfusion of blood and blood products.

1.4 The Most Responsible Health Practitioner shall consider the nature, risks, consequences and alternatives of the Treatment/Procedure. Where the Most

Responsible Health Practitioner determines that Express Consent is required to evidence the Patient's agreement to the Treatment/Procedure(s):

- a) Verbal consent shall be documented by the Most Responsible Health Practitioner in the Patient's Health Record; and/or
 - b) Written consent shall be documented by the Most Responsible Health Practitioner through obtaining the signature of the Patient on the Consent Form, which shall then be attached to the Patient's Health Record. Prior written consent shall not be obtained whenever analgesic, narcotic or anaesthetic agents will significantly affect the Patient's level of consciousness.
- 1.5 Implied Consent may be presumed in (but is not limited to) circumstances where the Patient presents voluntarily for an examination, investigation, minor or less invasive Treatment/Procedure(s) which the Most Responsible Health Practitioner determines does not require Express Consent.
- a) Implied Consent must still be informed.
 - b) The Most Responsible Health Practitioner should be satisfied that the circumstances or the actions of the Patient imply permission for the examinations, investigations and Treatment/Procedure(s) proposed. If there is any doubt that there is Implied Consent, the Most Responsible Health Practitioner shall obtain Express Consent from the Patient.

2. Accountability

- 2.1 The accountability to obtain Informed Consent shall rest with the Most Responsible Health Practitioner who is providing the specific Treatment /Procedure(s). In most circumstances, the Most Responsible Health Practitioner is a physician but may be another Health Practitioner who is providing the Treatment /Procedure(s).
- 2.2 The Most Responsible Health Practitioner remains accountable for the Consent Process, although more than one Health Practitioner may be involved in providing the Treatment/Procedure(s).
- 2.3 **Exception:** Sections 2.1 and 2.2 do not apply in the case of human tissue and organ donation. See procedure: Consent to Treatment/Procedure(s): Human Tissue and Organ Donation, section 4.

3. Capacity

- 3.1 An Adult Patient is presumed to have Capacity and is able to make decisions until the contrary is determined. Nevertheless, the Most Responsible Health Practitioner is required, in every case, to satisfy themselves that the Patient has the requisite Capacity to make Treatment decisions and is not unduly influenced by third parties. Capacity for a particular Patient can change depending on changes to his/her mental and physical health and Health Practitioners must be vigilant in satisfying themselves

about Capacity for each and every Treatment/Procedure(s). The Adult Patient's entitlement to make decisions based on his or her values and beliefs should be supported subject to exceptions under the *Mental Health Act*.

- 3.2 A Patient under the age of eighteen (18) years is presumed to be a Minor Patient without Capacity, unless assessed and determined to be a Mature Minor.
- 3.3 A Minor Patient who is assessed and determined as capable of appreciating the nature, risks and consequences of a Treatment/Procedure(s), including the ethical, emotional and physical aspects, shall be considered a Mature Minor:
- a) Health Practitioners shall conduct the assessment for a Mature Minor by asking questions in order to determine whether the Minor Patient has the intelligence and maturity to provide consent for a Treatment/Procedure(s) without the input of his/her Legal Representative(s).
 - b) The outcome of the assessment shall be documented in the Patient's Health Record.
- 3.4 A Patient may have Capacity even if they are unable to communicate verbally. Health Practitioners have a duty to facilitate communication with the Patient by any means that enables the Patient to be understood.
- 3.5 Where a Patient does not have Capacity to make a Treatment/Procedure(s) decision, the decision-making authority of an Alternate Decision-Maker should be recognized in accordance with applicable legislation.

4. Providing Relevant Information

- 4.1 The Most Responsible Health Practitioner shall give the Patient, or ensure the Patient has received, the information that a reasonable person would require to understand the proposed specific Treatment/Procedure(s) and to make an informed decision including, but not limited to, information about:
- a) the condition for which the Treatment/Procedure(s) is proposed;
 - b) the nature of the proposed Treatment/Procedure(s), including "basket(s)" of Procedures where clinically indicated and approved;
 - c) the risks and benefits of the proposed Treatment/Procedure(s) that a reasonable person in the Patient's circumstances would expect to be told about (if the Most Responsible Health Practitioner becomes aware of particular circumstances of the Patient that might affect the information they would want or his/her Treatment decisions, the Most Responsible Health Practitioner is responsible for addressing those particular circumstances with further information as appropriate);
 - d) alternatives to the proposed Treatment/Procedure(s); and

e) the likely consequences of not undertaking the Treatment/Procedure(s).

4.2 Consent is not valid if obtained in circumstances of fraud or through coercion. All information provided to the Patient must be accurate and understandable by the Patient.

5. Understanding

5.1 The Most Responsible Health Practitioner involved in the Consent Process should communicate in a manner appropriate to the Patient's ability to understand. This includes addressing barriers to communication including, but not limited to: hearing, sight, language, culture, literacy, level of education, level of anxiety and stress, and environmental factors, including location of discussion.

5.2 The Most Responsible Health Practitioner involved in the Consent Process is responsible for providing the Patient with the opportunity to ask questions and for providing understandable answers.

5.3 The Patient should be given time, when it is clinically safe to do so, to reflect on the information prior to making a decision.

6. Decision-Making

6.1 The ability to provide consent rests solely with the Patient but the discussion of information leading to the decision being made is a shared process between the Patient and the Most Responsible Health Practitioner.

6.2 Consent must be voluntary (with certain exceptions under the *Mental Health Act*). The Patient must have the opportunity to accept or refuse a Treatment/Procedure(s) without fear, constraint, compulsion or duress.

6.3 A Patient's decision to refuse or proceed with a particular Treatment/Procedure(s) shall not prejudice the Patient's access to ongoing, future health care.

6.4 Consent discussions should not occur in circumstances where the Patient feels pressured or does not have a reasonable opportunity to reflect on the decision or ask questions. Specifically, except in emergency situations, consent discussions should not take place in the operating room or its environs.

7. Documentation

7.1 The Most Responsible Health Practitioner is responsible for ensuring appropriate documentation of the Consent Process and outcomes on the Patient's Health Record. Specifically, the following outcomes shall be documented:

- a) Agreement to the Treatment/Procedure(s);
- b) Refusal of the Treatment/Procedure(s) (see section 8);

c) Withdrawal of Consent previously given (see section 9).

7.2 All relevant legal documents including, but not limited to, court orders, personal directives, capacity assessments and evidence of the formal status of Alternate Decision-Makers shall be documented on the Patient's Health Record.

7.3 While the requirements for documentation outlined in a) above are met by appropriately filling in the applicable Consent Form where written consent has been deemed necessary, documentation on the Patient's Health Record regarding the consent discussion is highly recommended.

8. Refusal of Treatment / Procedure(s)

8.1 An Adult Patient determined to have Capacity to make Treatment decisions regarding a particular procedure, may refuse the Treatment/Procedure(s) on any grounds, even when it is clear that Treatment is necessary to preserve his/her life or health. In this instance, the Treatment/Procedure(s) shall NOT be carried out, even if failure to provide such a Treatment/Procedure(s) may result in the Patient's death. This section is subject to situations in which a Treatment/Procedure(s) is ordered in accordance with applicable legislation.

8.2 The Alternate Decision-Maker for an Adult Patient lacking Capacity may refuse a Treatment/Procedure(s) as per applicable legislation, with the following exceptions:

- a) Specific Decision-Makers cannot make mental health decisions for Formal Patient(s) or person(s) subject to Community Treatment Orders;
- b) Specific Decision-Makers cannot make health care decisions where a decision respecting the provision of, withdrawal of, or withholding of health care would be likely to result in the imminent death of the Adult;
- c) The Alternate Decision-Maker cannot refuse Treatment on behalf of a Formal Patient when a Treatment /Procedure(s) has been ordered by a review panel under applicable mental health legislation; and
- d) The Alternate Decision-Maker cannot refuse or alter a Treatment/Procedure(s) that is ordered in accordance with applicable legislation.

8.3 In the event that a Mature Minor, or the Legal Representative for a Minor, refuses to provide consent for essential medical, surgical or other remedial Treatment necessary for the health or well-being of the Mature Minor or Minor, the Most Responsible Health Practitioner shall forthwith report this refusal to the Director of Child and Family Services Authority.

- a) A Mature Minor may give or refuse consent to Treatment/Procedure(s), and his/her Legal Representative cannot override the Mature Minor's decision.

- b) The Director of Child and Family Services Authority may seek a court order authorizing Treatment/Procedure(s).

8.4 If a Patient refuses a Treatment/Procedure(s), the Most Responsible Health Practitioner must explain the risks and consequences of the refusal to the Patient.

- a) This explanation can be witnessed by a second Health Practitioner.
- b) The Most Responsible Health Practitioner shall document the refusal on the Patient's Health Record.

9. Withdrawal of Consent

- 9.1 An Adult Patient with Capacity to make the Treatment decision may, at any time, withdraw consent previously given.
- 9.2 A Specific Decision-Maker may, at any time, withdraw consent previously given, except in certain circumstances. See the applicable procedure for details.
- 9.3 In the event that a Mature Minor, or the Legal Representative for a Minor, withdraws consent for essential medical, surgical or other remedial Treatment necessary for the health or well-being of the Mature Minor or Minor, the Most Responsible Health Practitioner shall forthwith report this withdrawal of consent to the Director of Child and Family Services Authority.
- 9.4 Upon a valid withdrawal of consent, the Most Responsible Health Practitioner shall stop providing the Treatment/Procedure(s) and revisit the Consent Process.
- 9.5 The Patient may provide consent again at any time following an Informed Consent discussion.
- 9.6 The Most Responsible Health Practitioner shall advise the Patient of the risks of not proceeding with the Treatment/Procedure(s) and document the Patient's withdrawal of consent on the Patient's Health Record, the circumstances of the withdrawal, the explanation that was provided to the Patient and the outcome of the discussion.
- 9.7 Notwithstanding this section 9, a Patient's withdrawal of consent does not prevent a Treatment/Procedure from proceeding when it has been ordered in accordance with applicable legislation.

10. Duration of Consent

- 10.1 A new consent shall be obtained and if that consent was previously obtained in writing, then a new Consent Form shall be completed, or changes made to the original form and initialled by the Patient and the Most Responsible Health Practitioner (and witnessed), when one or more of the following occurs:
 - a) The Patient's condition has materially changed;

- b) The medical knowledge about the Patient's condition or the Treatment available has materially changed; or
- c) There has been a refusal to a portion of the Treatment or procedure originally planned or a refusal regarding the involvement of particular individuals in the Treatment or procedure (i.e. medical trainees).

10.2 The Most Responsible Health Practitioner is responsible for confirming the validity of consent prior to the delivery of the Treatment/Procedure(s).

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.

Alberta Health Services Setting means any environment where Treatment/Procedures and other health care are delivered by, on behalf of or in conjunction with Alberta Health Services.

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.

Co-Decision-Maker means a person selected by the Patient and appointed by the Court to make decisions in partnership with the Patient, when the Patient has significantly impaired capacity but can still participate in decision-making.

Community Treatment Order means an order issued under Section 9.1 of the *Mental Health Act*.

Consent Form means an Alberta Health Services approved form of documentation that can be used to provide evidence of the outcome of the Consent Process, that is, agreement to or refusal of a Treatment/Procedure.

Consent Process means a discussion or series of discussions and interactions between the Most Responsible Health Practitioner and Patient or his/her 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.

Express Consent means direct, explicit agreement to undergo a Treatment/Procedure(s), given either verbally or in writing.

Formal Patient means a Patient detained in a designated mental health facility under two admission certificates or two renewal certificates, in accordance with the *Mental Health Act*.

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 the agreement and verify it qualifies under legislation; e.g. agreement between the 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 the *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 a copy of the 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 according to the *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 to make decisions on behalf of the Adult Patient when the Adult Patient lacks Capacity.

Health Practitioner means an individual who provides Treatment/Procedure(s) within his/her scope of practice and position description.

Health Record means the Alberta Health Services legal record of the Patient's diagnostic, Treatment and care information.

Implied Consent means consent inferred from the Patient's or Alternate Decision-Maker's (if applicable) actions and surrounding circumstances.

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.

Legal Representative means the following in relation to a Minor, as applicable:

- a) Guardian;
- b) Nearest Relative as defined in the *Mental Health Act* who has the authority to consent to Treatment for a Minor Formal Patient or Minor who is subject to a Community Treatment Order

Mature Minor means a person aged less than eighteen (18) years, who has been assessed and determined as having the intelligence and maturity to appreciate the nature, risks, benefits, consequences, and alternatives of the proposed Treatment/Procedure, including the ethical, emotional and physical aspects.

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

Most Responsible Health Practitioner 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 his/her practice.

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/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.

Specific Decision-Maker means a nearest relative who may be selected from a hierarchy of relatives to make a specific decision on behalf of the Patient according to the *Adult Guardianship and Trusteeship Act*.

Treatment/Procedure means a specific treatment, investigative procedure(s), or series of treatments/procedures planned to manage a clinical condition.

CROSS-REFERENCES

- **Appendices**
 - Appendix "A" – Overview of the definition of "Guardian" as set out in section 20 of the *Family Law Act*.
- **Alberta Health Services Procedures**
 - 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 Minors
- 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 Procedure: Consent to Treatment/Procedure(s): Human Tissue and Organ Donation
- **Alberta Health Services Forms**
 - Consent to Specific Treatment/Procedure (#09741)
 - Consent to Human Tissue and/or Organ Donation (#09816)
 - Community Treatment Decisions Consent (#09565)
- **Legislation**
 - *Adult Guardianship and Trusteeship Act*
 - *Child, Youth and Family Enhancement Act*
 - *Family Law Act*
 - *Health Information Act*
 - *Health Professions Act*
 - *Human Tissue and Organ Donation Act*
 - *Mandatory Testing and Disclosure Act*
 - *Mental Health Act*
 - *Personal Directives Act*
 - *Protection for Persons in Care Act*
 - *Protection of Children Abusing Drugs Act*
 - *Public Health Act*
- **Provincial Standards**
 - College of Physicians and Surgeons of Alberta: Standards of Practice

REVISIONS

August 1, 2011

APPENDIX "A"

The following is an 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*:

Children conceived without assisted reproduction:	Children conceived with assisted reproduction and whose birth mother is the intended parent:	Children who were conceived with assisted reproduction and whose birth mother is a surrogate:
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. <i>*see below for who is presumed to be the biological father.</i>	The birth mother will be considered to be one parent.	Until there is a Court Order declaring parentage, the surrogate remains the only legal parent.
	The other parent will depend on how the Embryo was created: 1. If the embryo was created from the intended male parent's sperm, then the other legal parent is the intended male parent. 2. If the embryo was created	Once the surrogate has relinquished her parental rights, a Court Order will declare the proper legal parents.

	<p>from donated sperm, then the person who was married to or in a conjugal relationship with the birth mother AND consented to be a parent at the time of conception is the other parent.</p>	
<p>If there is a dispute over parentage, a court order may be sought to declare that someone is or is not a parent of a particular child. For Adoptions, a Court Order will be provided.</p>		

INTENTION***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 cohabitated 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 (Court may find other evidence to be that of Intention);
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