Alberta Health Services

PROCEDURE
LEVEL 1

TITLE
CONSENT TO TREATMENT / PROCEDURE(S) ADULTS WITH CAPACITY

DOCUMENT #
PRR-01-01

PARENT DOCUMENT LEVEL
LEVEL 1

PARENT DOCUMENT TITLE
Consent to Treatment/ Procedure(s)

APPROVAL LEVEL
Alberta Health Services Executive

SPONSOR
Quality and Service Improvement
Senior Physician Executive

CATEGORY
Patient Rights and Responsibilities

INITIAL APPROVAL DATE
October 31, 2010

INITIAL EFFECTIVE DATE
October 31, 2010

REVISION EFFECTIVE DATE
October 31, 2010

NEXT REVIEW
October 31, 2012

If you have any questions or comments regarding the information in this procedure, 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.

OBJECTIVES

This procedure will set out the appropriate actions to be taken during the Consent Process for **Adults with Capacity**, that is, a Patient who is fully able to participate independently in the Consent Process or with the support of a Supported Decision Maker.

This procedure will address:

1. Who May Give Consent
2. Consent is Required
3. Exceptions to Consent
4. Accountability
5. Consent Process
6. Duration of Consent
7. Refusal of Treatment/Procedure
8. Withdrawal of Consent

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 services providers as necessary). This procedure does not limit any legal rights to which you may otherwise be entitled.

PROCEDURE

1. Who May Give Consent

1.1 Patients who are over the age of eighteen (18) years, and who have Capacity.

1.2 Patients may choose to select a Supported Decision-Maker to assist in the decision-making process according to the *Adult Guardianship and Trusteeship Act*. The Patient is still responsible for making his or her own decision(s) and providing consent. The Supported Decision-Maker may communicate the Patient's decision or may assist in communicating the Patient's decision.

2. Consent is Required

2.1 Before a Treatment or Procedure is provided, there must be Express or Implied Consent, unless a valid exception applies (see section 3 for exceptions).

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.

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

2.3 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 2.3, and with the exception of an emergency situation (in an emergency, please refer to section 3.1) Express written consent shall be obtained for the transfusion of blood and blood products.

2.4 The Most Responsible Health Practitioner shall consider the nature, risks, consequences and alternatives of the Treatment/Procedure(s). 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.

2.5 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.

3. Exceptions to Consent

3.1 Emergency Health Care:

a) If the Patient requires emergency health care and has Capacity and is able to participate, the Most Responsible Health Practitioner should proceed with the Consent Process as outlined in this procedure, where practical, given timing and safety considerations.

b) If the Patient requires emergency health care but lacks Capacity to participate in the Consent Process, refer to the Alberta Health Services Procedure: Consent to Treatment /Procedure(s): Adults with Impaired Capacity and Adults who Lack Capacity.

3.2 Exceptional Circumstances: the requirement for Informed Consent may be overridden by a warrant, subpoena, court order or according to applicable legislation (for example: treatment order under the *Mental Health Act*; orders under the *Public Health Act*; orders under the *Mandatory Testing and Disclosure Act*).

4. Accountability

4.1 The accountability to obtain Informed Consent shall rest with the Most Responsible Health Practitioner who is proposing and/or delivering 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).

4.2 The Most Responsible Health Practitioner remains accountable for the Consent Process, although more than one Health Practitioner may be involved in the delivery of the Treatment/Procedure(s).

4.3 **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.

5. Consent Process

The provision of consent, and determination of the Capacity to Consent, must relate to a specific Treatment/Procedure(s) or plan of Treatment/Procedure(s).

5.1 Determination of Capacity to Provide Informed Consent

a) A Patient is presumed to have Capacity and is able to make decisions until the contrary is determined. The Patient's ability to make decisions based on his or her values and beliefs should be supported.

b) A Patient may have Capacity even if he/she is unable to communicate verbally. Health Practitioners have a duty to facilitate communication with the Patient, and his/her Supported Decision-Maker, if applicable, by any means that enables the Patient to be understood.

5.2 Providing Relevant Information

a) The Most Responsible Health Practitioner shall give the Patient, and his/her Supported Decision-Maker if applicable, or ensure the Patient and his/her Supported Decision-Maker, if applicable, 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:

- the condition for which the Treatment/Procedure(s) is proposed;
- the nature of the proposed Treatment/Procedure(s), including "basket(s)" of Procedures where clinically indicated and approved;
- 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 has a duty to address those particular circumstances with further information as appropriate);
- alternatives to the proposed Treatment/Procedure(s); and
- the likely consequences of not undertaking the Treatment/Procedure(s).

b) 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.

5.3 Understanding of Information

a) Consent will be considered valid if the Most Responsible Health Practitioner is of the opinion that the Patient understands the purpose, nature, risks, benefits, consequences and alternatives of the proposed Treatment /Procedure(s):

- The Health Practitioner(s) involved in the Consent Process should communicate with the Patient in a manner appropriate to the Patient's ability to understand. The Health Practitioner(s) must review any 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.
- The Patient shall be given the opportunity to ask questions and to receive understandable answers.
- If the Patient is unable to understand the discussion or to read or understand the Consent Form, the contents of the Consent Form shall be read and explained to the Patient in the presence of a witness and with the assistance of an interpreter as necessary.
- The Most Responsible Health Practitioner may allow, at the Patient's request, the Patient's spouse, Supported Decision Maker (if applicable),or any relatives or friends that accompany the Patient and offer their assistance, to help the Patient to understand or demonstrate an understanding of the information. That individual may not be the witness to the Consent Form.
- The Patient should be given time, when it is clinically safe to do so, to reflect on the information prior to making a decision.

5.4 Decision-Making

a) 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, their Supported Decision-Maker if applicable, and the Most Responsible Health Practitioner.

b) If the Patient is able to participate in the Consent Process, with a Supported Decision Maker if applicable, consent should not be obtained after the administration of sedating medication, or while the Patient is under the influence of drugs, alcohol or in shock, as the circumstances may be such to render the Patient incapable of giving informed and voluntary consent.

c) A Patient's decision related to Treatment/Procedure(s) should be made without fear, constraint, compulsion or duress.

d) 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.

5.5 Documentation of Consent Process

a) The Most Responsible Health Practitioner providing the Treatment/Procedure shall ensure that the Consent Process has been followed and that the Consent Process and outcome are documented appropriately in the Patient's Health Record. Specifically, the following outcomes shall be documented:

- Agreement to the Treatment/Procedure
- Refusal of the Treatment /Procedure (see section 7)
- Withdrawal of Consent previously given (see section 8)

b) 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.

c) Prior to the Patient signing the Consent Form, the Most Responsible Health Practitioner shall ensure that the name of the specific Treatment/Procedure(s) is filled in. No abbreviations shall be used on the Consent Form.

d) Consent may be obtained in the Most Responsible Health Practitioner's office if applicable. Completed Consent Forms shall be forwarded to the applicable Alberta Health Services setting where the Patient will be receiving the Treatment/Procedure(s).

e) Completed Consent Forms required for Treatment/Procedure(s) may be in a faxed or scanned format. Where possible, and at the earliest opportunity, the original Consent Form shall be obtained and placed on the Patient's Health Record.

f) In the event that an interpreter is used, the interpreter shall complete the relevant documentation on the Consent Form.

g) A blind or disabled person's "mark" is recognized as a valid signature on the Consent Form.

h) The Consent Form shall be added to the Patient's Health Record.

5.6 Witnessing a Consent or a Refusal of Treatment

Written Consent should be witnessed:

a) Any person, other than a relative of the Patient, the Most Responsible Health Practitioner or the interpreter for the Patient, may witness the signing of a Consent Form.

b) Before acting as a witness, the witness shall confirm the Patient's identity or if the signee is not the Patient, request to see a form of identification. The witness shall also confirm that the person making a mark on behalf of the Patient has been asked to do so by the Patient. Witnessing a Consent Form indicates ONLY that the witness observed the Consent Form being signed and is not evidence of the Consent Process.

c) In the event that the Patient expresses doubt about the Consent Process and requests further explanation, the witness shall not sign the Consent Form and the Most Responsible Health Practitioner shall be notified.

6. Duration of Consent

6.1 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/Procedure(s) originally planned or a refusal regarding the involvement of particular individuals in the Treatment/Procedure(s) (e.g. medical trainees).

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

7. Refusal of Treatment / Procedure

7.1 Subject to Section 3.2, a Patient may refuse a Treatment/Procedure(s) on any grounds, even when it is clear that the Treatment/Procedure(s) is necessary to preserve his/her life or health. The Most Responsible Health Practitioner shall respect the wishes of the Patient and the Treatment/Procedure(s) shall NOT be carried out, even if failure to provide such an intervention may result in the Patient's death.

7.2 Patients who refuse the infusion of blood products or who carry written and signed statements refusing the infusion of blood products shall have their wishes respected.

7.3 If a Patient refuses a Treatment/Procedure(s), the Most Responsible Health Practitioner shall explain the risks and clinical consequences of the refusal to the Patient, without creating the perception of coercion.

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.

7.4 Subject to 3.2, a Patient may refuse to consent to blood testing for HIV, Hepatitis B, and Hepatitis C. In the event of the exposure of a Health Practitioner to a Patient's bodily fluids where a blood borne virus is suspected, and the Patient refuses to consent to blood testing, the Health Practitioner should immediately contact Workplace Health & Safety.

8. Withdrawal of Consent

8.1 Subject to 3.2, a Patient may, at any time, withdraw a consent previously given.

8.2 It is important that the Patient understands the consequences of withdrawing consent for the Treatment/Procedure(s). The Most Responsible Health Practitioner must advise the Patient of the risks of not proceeding with the Treatment/Procedure. This discussion and the Patient's withdrawal of consent shall be documented on the Patient's Health Record. Specifically, the Patient's withdrawal of consent shall be noted on the consent form. Other documentation may include:

a) a summary of the information that was provided to the Patient about the Treatment/Procedure;

b) the Patient's reasons for withdrawing consent, if known; and

c) the expected outcomes of not receiving the Treatment/Procedure(s).

8.3 The Patient may provide consent again at any time following an Informed Consent discussion.

DEFINITIONS

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

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

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 under applicable mental health legislation, and persons subject to Community Treatment Orders, mental competence is addressed in section

26 of *Alberta's 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.

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

Health Practitioner means an individual who provides Treatment/Procedure(s) within their 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 (if applicable) actions and surrounding circumstances.

Informed Consent means the informed agreement of a Patient or Alternate Decision-Maker (if applicable) prior to the Patient undergoing a Treatment/Procedure(s) after being provided with the relevant information about the Treatment/Procedure(s), its risks and alternatives and the consequences of refusal.

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 their 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.

Supported Decision-Maker means a trusted person that the capable adult appoints pursuant to the *Adult Guardianship and Trusteeship Act* to assist him/her with accessing, collecting or obtaining information, making decision(s) and communicating his/her decision(s).

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

CROSS-REFERENCES

- **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 Impaired Capacity and Adults who Lack Capacity
- Alberta Health Services Procedure: Consent to Treatment/Procedures: Minors/Mature Minors
- Alberta Health Services Procedure: Formal Patients and Persons subject to Community Treatment Orders under the Mental Health Act
- Alberta Health Services Procedure: Consent to Treatment/Procedures: Human Tissue and Organ Donation
- Alberta Health Services Policy – Transmission of Information by Facsimile or Electronic Mail

- **Alberta Health Services Form**

- Consent to Specific Treatment/Procedure (#09741)
- **Legislation**
    - *Adult Guardianship and Trusteeship Act*
    - *Health Professions Act*
    - *Human Tissue and Organ Donation Act*
    - *Mandatory Testing and Disclosure Act*
    - *Mental Health Act*
    - *Public Health Act*
- **Provincial Standards**

- College of Physicians and Surgeons of Alberta: Standards of Practice

REVISIONS

October 31, 2010