

STANDARDS OF PRACTICE

Informed Consent & Determining Capacity to Consent

Commented [CD1]: Title changed to acknowledge capacity content.

Under Review: Yes Issued By: Council: January 1, 2010 Reissued by Council: June 1, 2016



The **Standards of Practice** of the College of Physicians & Surgeons of Alberta ("CPSA") are the **minimum** standards of professional behavior and ethical conduct expected of all regulated members registered in Alberta. Standards of Practice are enforceable under the Health Professions Act and will be referenced in the management of complaints and in discipline hearings. CPSA also provides Advice to the Profession to support the implementation of the Standards of Practice.

Note: a glossary of terms can be found at the end of this document. Glossary terms are indicated in teal with a "G" throughout this document.

PREAMBLE

The process of informed consent occurs when communication between a regulated member and a patient results in the patient's authorization or agreement to undergo a specific medical intervention.1

The obligation to ensure valid consent^G is obtained always rests with the regulated member proposing treatment. Regulated members are strongly advised to obtain express consent^G when the treatment is likely to be more than mildly painful, carries appreciable risk or will result in a minimally invasive procedure.² Patients should be presumed competent to give consent unless otherwise established.3

Regulated members should discuss consent with patients taking into account the patient's cultural, religious and social needs, as well as their values, beliefs⁴ and healthcare goals,⁵ which may require alternate approaches for delivering information and obtaining consent. How consent is obtained will differ for each patient and should always be viewed as an evolving process, rather than a point-in-time decision.²

Patients have the right to receive information and ask questions about recommended treatments so they can make well-considered decisions about care. Successful communication fosters trust and supports shared decision-making.

Terms used in the Standards of Practice:

¹ From the American Medical Association's Code of Medical Ethics - Informed Consent (2016).

² From CPSBC's <u>Consent to Treatment</u> (Apr. 2023).

³ From CPSNB's Informed Consent: Helping Patients Make Informed Decisions About Their Care (Oct. 2021).

⁴ From MCNZ's <u>Statement on Informed Consent</u> (June 2021).

⁵ From CMPA's "Helping patients make informed decisions" (Jan. 2022).

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^{• &}quot;Patient" includes, where applicable, the patient's legal guardian or substitute decision maker



STANDARD

- 1. A regulated member **must**:
 - a. obtain a patient's informed consent^G prior to an examination, assessment, treatment^G or procedure;
 - obtain a patient's consent prior to students or observers participating in the patient's care,
 - c. document consent in the patient's record including, but not limited to:
 - i. the information discussed;
 - ii. any specific risks that were highlighted;
 - iii. any request or concerns expressed;
 - iv. any decisions made and the reasons for them³;
 - v. if the patient declines information about their treatment;⁴ and
 - d. respect the right of a patient, legal guardian or substitute decision-maker to refuse, withhold or withdraw consent at any time. 67
- When obtaining consent for an examination, assessment, treatment or procedure, a regulated member must always:
 - clearly explain the rationale for the physical exam or procedure and what it will involve;
 - b. obtain express consent before proceeding ^G;
 - seek ongoing consent, as required, throughout the physical exam or procedure; and

Commented [CD2]: From <u>CPSNB</u>: echoes similar requirements from CPSA's *Restricted Activities* standard of practice.

Commented [CD3]: From CPSNB: ensures accurate account of consent process.

Commented [CD4]: From <u>CPSNS</u> and <u>CPSO</u>: ensures patient autonomy and preserves the physician-patient relationship.

Terms used in the Standards of Practice:

⁶ From CPSNS's <u>Patient Consent to Treatment</u> (Dec. 2016).

⁷ From CPSO's <u>Consent to Treatment</u> (Feb. 2021).

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- stop the physical exam or procedure immediately upon the patient's request.²
- A regulated member obtaining informed consent from a patient, or the patient's legal guardian or substitute decision-maker, must ensure the decision-maker:
 - a. is aware of their right to withdraw consent at any time;
 - b. is free of undue influence, duress or coercion in making the consent decision;
 - c. receives a proper explanation that includes, but is not limited to:
 - i. diagnosis reached;
 - ii. advised interventions and treatments;
 - iii. exact nature and anticipated benefits of the proposed examination, assessment, treatment or procedure;
 - iv. common risks and significant risks;
 - v. all reasonable treatment options available, and the associated common risks and significant risks;
 - vi. natural history of the condition and the consequences of forgoing treatment;
 - d. has the opportunity to have a conversation about the information provided, regardless of whether supporting documents (e.g., consent forms, patient education materials or pamphlets) are used to facilitate the provision of such information; and
 - e. demonstrates a <u>reasonable understanding</u> of the information provided and the reasonably foreseeable consequences of both a decision and a failure to make a decision.
- 4. If a patient is under the age of 18 years, a regulated member **must**:

Commented [CD5]: From the <u>American Medical Association</u>: ensures safety for both patient and regulated member.

Commented [CD6]: From <u>CMPA</u>: ensures patient can ask questions to understand treatment.

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- a. determine whether the patient is a mature minor^G with the capacity to give informed consent¹; and
- b. if the patient is not a mature minor, seek informed consent from the patient's legal guardian, in accordance with legislation¹.
- 5. If an adult patient lacks capacity^G to give informed consent, a regulated member must seek informed consent from the patient's legal guardian or substitute decisionmaker, in accordance with legislation.
- If a regulated member has reasonable grounds to believe an informed consent 6. decision by a legal guardian or substitute decision-maker is not in the best interests of the patient, they must seek advice from appropriate parties^G depending on the situation.
- 7. A regulated member who assesses the capacity of a patient to give informed consent must:
 - a. use accepted capacity assessment processes^G;
 - attempt to obtain the patient's agreement to participate; and
 - inform the patient of the nature and consequences of the capacity assessment.
- 8. A regulated member obtaining informed consent for a patient to participate in health research must comply with CPSA's Human Health Research standard of practice.
- 9. A regulated member **may** proceed without consent **if** it is a medical emergency⁶ where the patient, legal quardian or substitute decision-maker is unable to
 - as soon as the patient, legal guardian or substitute decision-maker is able to make decisions and regains the ability to give consent, a proper and informed consent must then be obtained for any additional treatment;² and
 - the reasons for going ahead with treatment must be documented in the patient's record.3

Commented [CD7]: From MCNZ: ensure patient needs/desires taken into consideration.

Commented [CD8]: From CPSBC: added for clarity.

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- A regulated member may only delegate responsibility for obtaining informed consent to another healthcare professional when confident the delegate has the appropriate knowledge, skill and judgment to meet the expectations of this standard, in accordance with the Responsibility for a Medical Practice and Restricted Activities standards of practice.
 - If the delegate does not agree to accept responsibility for obtaining informed consent on behalf of the regulated member, the regulated member **must** obtain consent themselves.
 - The regulated member who performs the treatment or investigation is ultimately responsible for ensuring informed consent is provided.
- 11 If a regulated member is unsure whether the consent obtained is valid, they must not provide the treatment until assured valid consent has been obtained.

GLOSSARY

Accepted capacity assessment: a capacity assessment is done to determine if an adult can make personal/financial decisions and can understand the consequences; 8 Alberta Health (AH) sets out provincial quidelines regarding capacity assessments.

Appropriate parties: will depend on each individual situation and may include following institutional guidance, engaging the health care system/government agencies or seeking legal input (e.g., the Canadian Medical Protective Association).

Capacity: an individual who is able to understand the nature and anticipated effect of proposed medical treatment and alternatives, and to appreciate the consequences of refusing treatment, is considered to have the necessary capacity to give valid consent.9

Informed consent: a patient must have an adequate understanding of the proposed examination, assessment, treatment or procedure, including the expected outcome, potential risks and benefits, as well as available alternatives, to make an informed decision.9

Express consent: consent that is expressed by the patient either in writing or verbally. Express consent should be obtained when the treatment is likely to be

Terms used in the Standards of Practice:

Commented [CD9]: Added for clarity.

Commented [CD10]: From CMPA: added for clarity to ensure safety for patients and regulated members

⁸ From AH's "About capacity assessment."

⁹ From CMPA's "Consent: A guide for Canadian physicians" (Aug. 2023).

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more than mildly painful, carries appreciable risk or will result in ablation of a bodily

Implied consent: consent that that is implied by the patient's actions or behaviours (e.g., volunteering a history, answering questions, submitting to an examination without objection). Regulated members should be reasonably confident consent is implied: if there is any doubt, express consent is preferrable.9

Valid Consent: for consent to be considered valid, it must be voluntary (i.e., free of duress or coercion), the patient must have the capacity to consent (i.e., able to understand the nature and benefits/risk of proposed treatment) and they must have been properly informed.9

Mature minor: an individual under the age of 18 who can understand and appreciate the nature, risks and consequences of a proposed treatment/procedure and can provide consent without the input of their legal representative. For more information, please refer to the Informed Consent for Minors Advice to the Profession document.

Medical emergency: to declare any clinical situation an emergency for which consent is not required, there must be demonstrable severe suffering or an imminent threat to the life of the patient. Treatments must be limited to those necessary to prevent prolonged suffering or to deal with imminent threats to life, limb or health.²

Reasonable understanding: what a reasonable patient in the particular patient's position would understand.10

Treatment: the management and care of a patient for a therapeutic, preventative, palliative, diagnostic, cosmetic or health-related purpose. Includes a course of treatment, plan of treatment or community treatment plan. Examples include, but are not limited to, physical examinations, investigations, and surgical interventions.² ¹¹

RELATED STANDARDS OF PRACTICE

- Code of Ethics & Professionalism
- Human Health Research
- Medical Assistance in Dying

Terms used in the Standards of Practice:

¹⁰ From CMPA's "Informed Consent" (Nov, 2022).

¹¹ From CPSNL's <u>Consent to Treatment</u> (June 2019).

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- Responsibility for a Medical Practice
- Supervision of Restricted Activities

COMPANION RESOURCES

- Advice to the Profession: Informed Consent for Adults
- Advice to the Profession: Informed Consent for Minors
- Advice to the Profession: Legislated Reporting & Release of Medical Information
- Office of the Public Guardian's Guide to Capacity Assessment under the Personal Directives Act
- Office of the Public Guardian's Resources for Capacity Assessors
- CMPA's Consent: A guide for Canadian Physicians
- CMPA's Informed consent: Overview and objectives
- CMPA's Informed consent: Why and when do we need consent?

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