QUINTE HEALTHCARE CORPORATION

Consent – Consent for Treatment

Title: Consent – Consent for Treatment		**Policy No:**	**2.10.3**
		Original Issue Date:	November 1998
Manual:	**Administration**	**Last Review/Revision Date:**	May 29, 2014
Department:	**Corporate**	**Policy Lead:**	Director of Quality and Patient Safety
Approved By:	**Quality and Patient Safety Committee**		

1. POLICY

The purpose of this policy is to ensure practices at Quinte Healthcare Corporation (QHC) are in keeping with legislation of all professional health regulatory colleges, promotes patient autonomy, and guides the provision of ethically sound care. QHC recognizes that the mere signing of a consent form by a patient does not in itself provide conclusive proof that the patient in fact made an informed consent. Rather, the consent form in the health record acts as a record of the fact that the consent process took place.

It is important to be satisfied that the patient has provided a valid informed consent, for all acts and procedures as defined in this policy, based on the information that they received and their level of understanding. The consent process is based on effective communication and trust between the patient and the treating health professional.

In keeping with the Health Care Consent Act (1996), informed consent to treatment is required from all patients or their substitute decision-maker (SDMs) for all acts and procedures as *defined in this policy,* administered by health care practitioners. Capable patients have the legal right to refuse treatment. The following elements of consent must be present for consent to be valid:

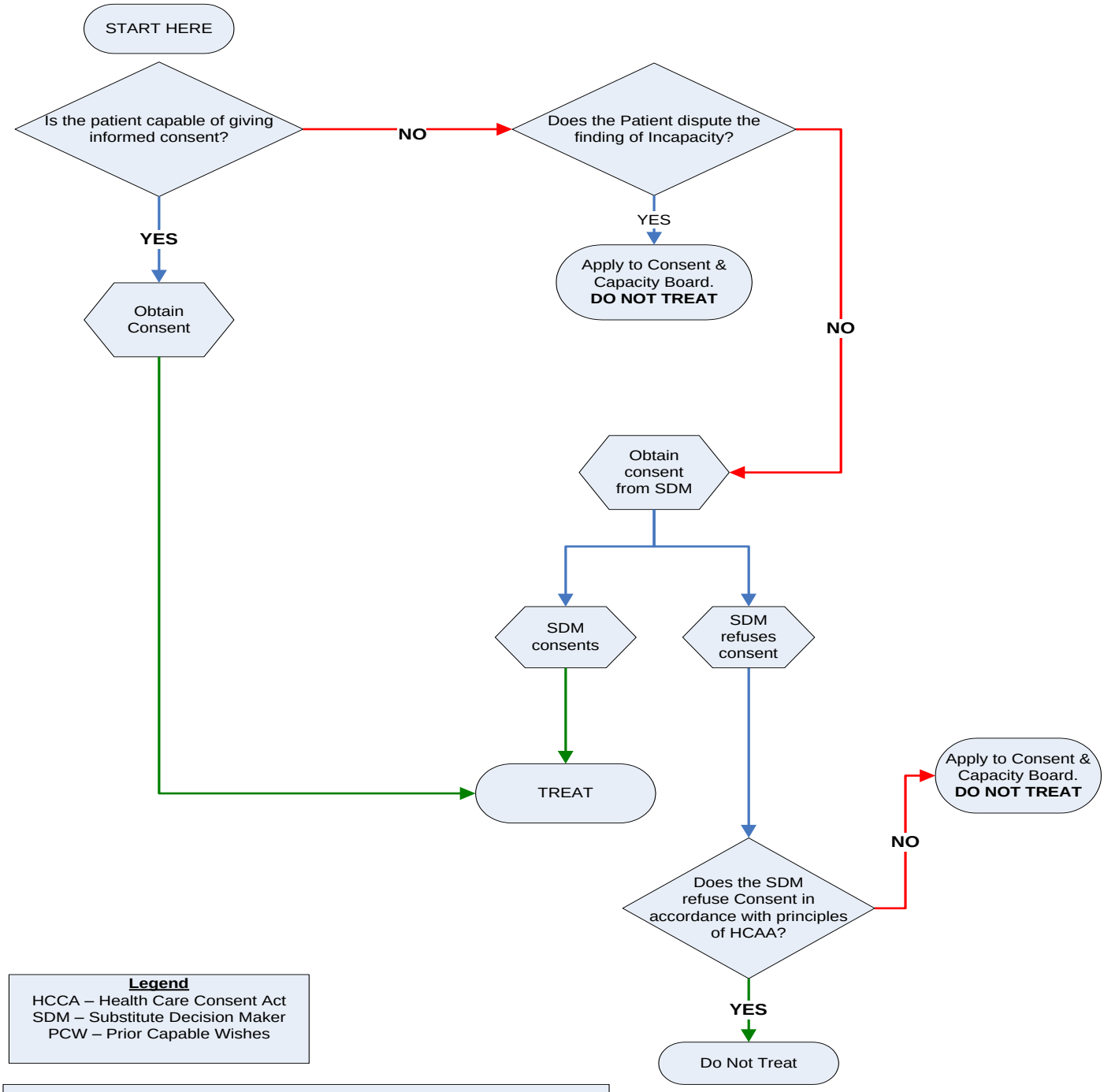
a. Consent must be related to treatment
b. Consent must be informed

c. Consent must be voluntary (not obtained through fraud or misrepresentation)
d. The person giving consent must be capable of comprehending the decision to either consent to or refuse treatment

Under this policy an additional requirement is for a consent form to be signed by the patient or SDM. (See *Appendix C* for Consent to Treatment form)

CONSENT TO TREATMENT FLOW CHART – Non Emergent

NOTE: This algorithm only applies to treatments under the HCCA



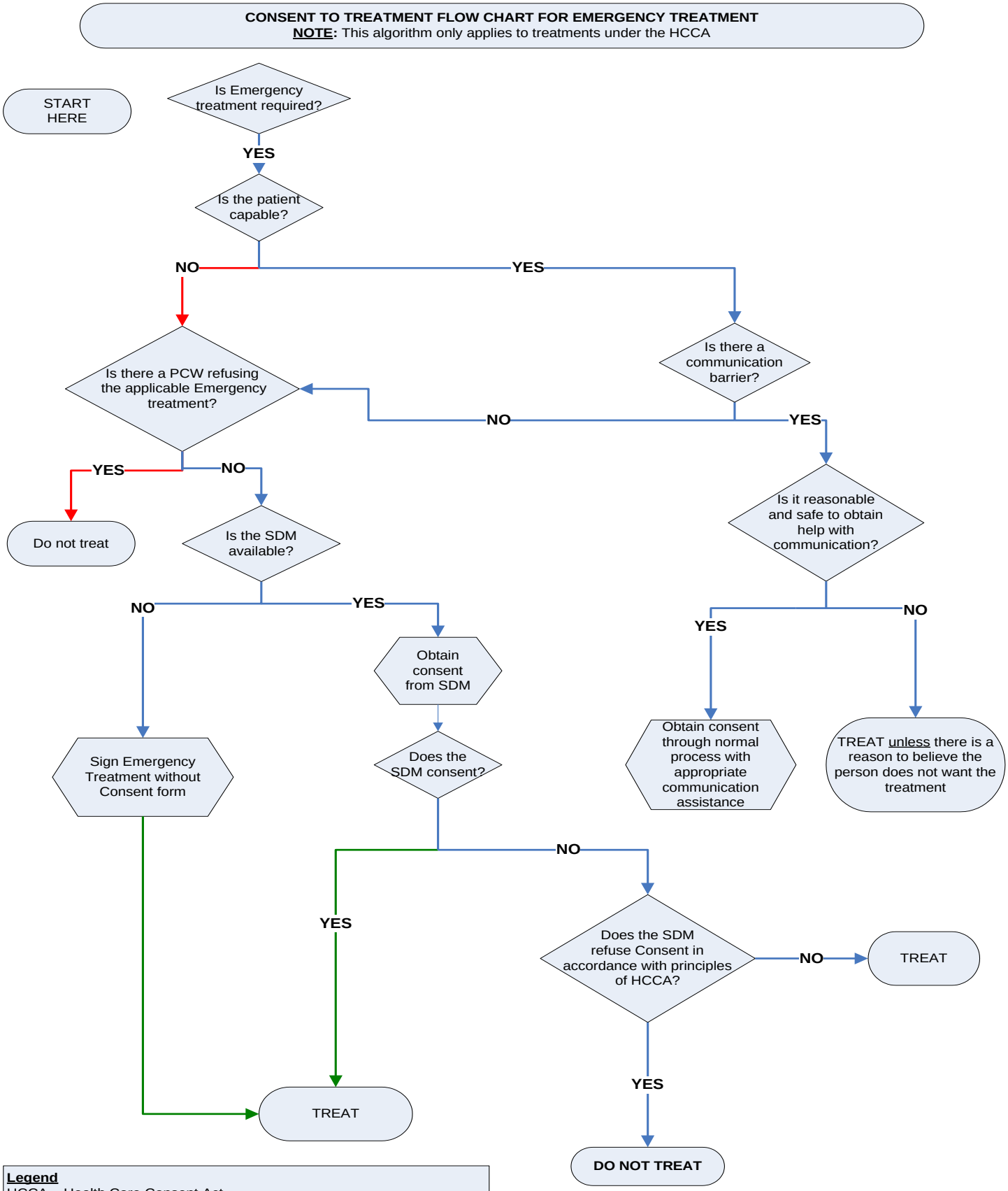
Legend
HCCA – Health Care Consent Act
SDM – Substitute Decision Maker
PCW – Prior Capable Wishes

Resources
Consent & Capacity Board:
Phone: 1-866-777-7391 (Toll Free)

Coordinator of Risk Management & Patient Concerns: x2033

To View the Health Care Consent Act (1996) and Substitute Decisions Act (1992), go to www.e-laws.gov.on.ca under Consolidated Law

Bioethics Committee:
X 2934


CONSENT TO TREATMENT FLOW CHART FOR EMERGENCY TREATMENT
NOTE: This algorithm only applies to treatments under the HCCA
START HERE
Is Emergency treatment required?
YES
Is the patient capable?
NO
YES
Is there a PCW refusing the applicable Emergency treatment?
Is there a communication barrier?
NO
YES
YES
NO
Do not treat
Is the SDM available?
Is it reasonable and safe to obtain help with communication?
NO
YES
YES
NO
Obtain consent from SDM
Sign Emergency Treatment without Consent form
Does the SDM consent?
Obtain consent through normal process with appropriate communication assistance
TREAT unless there is a reason to believe the person does not want the treatment
NO
YES
Does the SDM refuse Consent in accordance with principles of HCCA?
NO
TREAT
YES
TREAT
DO NOT TREAT
Legend
HCCA – Health Care Consent Act
SDM – Substitute Decision Maker
PCW – Prior Capable Wishes (advance directives)
Note: as per HCCA (s) 26 the person with PCW/advance directives must be 16 years or older to be binding

Definitions:

Informed Consent: implies that the patient (or the SDM) received information in order to make a decision and includes:

- the nature of the treatment(s)
- the expected benefits
- the material risks and side effects
- alternative courses of action
- the likely consequences of not having the treatment

Capacity means a patient is presumed to be capable unless a healthcare Practitioner (e.g. physician, nurse, physiotherapist) has reasonable grounds to believe the patient is incapable to consent to the specific treatment they are proposing. The person should be able to understand the information that is relevant to making a decision about the treatment, as well, must be able to appreciate the foreseeable consequences of a decision or lack of decision" (HCCA, section 4,1996).

The following observations may prompt concern about capacity:

- Evidence of confused or delusional thinking
- Unable to make a settled choice
- Judgment impaired by alcohol or drugs
- Other observations that give rise to concern about the patient's capacity

The test for capacity is the ability to make a *reasoned* decision, as opposed to what others may view as a *reasonable* decision. A patient is not judged capable or incapable across the board, but rather capacity is assessed in relation to each decision that must be made" (Granger & Margolese, 1997).

Implied Consent: is consent that occurs when surrounding circumstances are such that a reasonable person believes that consent had been given, although no direct, express or explicit words of agreement had been uttered. This may be an action or gesture (i.e. someone who presents their arm for injection or opens their mouth for an examination).

Express Consent: is directly given, either orally or in writing. It is given by the patient or SDM, is positive, direct, unequivocal consent, requiring no inference or implication to supply its meaning.

Healthcare Practitioner (HP): refers to a member of an Ontario regulated health profession, working at QHC.

Prior Capable Wishes: instructions, expressed by an incapable person while he/she was still capable and at least 16 years of age, regarding the type of treatments or procedures that he/she would or would not want to receive in various situations.

Advance Directive: an expression of a capable person's Prior Capable Wishes, and may be expressed orally, in writing or in any other medium (e.g. video).

Treatment is "anything that is done for therapeutic, preventative, palliative, diagnostic, cosmetic or other health care related purpose, and includes a course of treatment, plan of treatment or community treatment plan, but **does not** include:

a) The assessment for the purpose of this Act of a person's capacity with respect to a treatment, admission to a care facility or a personal assistance service or the assessment for the purpose of the Substitute Decisions Act;
b) The assessment or examination of a person to determine the general nature of the person's condition;
c) The taking of a person's health history;
d) The communication of an assessment or diagnosis;
e) The admission of a person to a hospital or other facility;
f) A personal assistance service;
g) A treatment that in the circumstances poses little or no risk of harm to the person;
h) Anything prescribed by the regulations as not constituting treatment – (HCCA, s. 2,1996).

*It is important to note that although the Act contains exceptions to the definition of "treatment", it is advised that health care providers obtain consent for all patient-health care provider interactions. For many of these interactions, unless the treatment is covered by another policy, the health care provider can rely on implied consent. [1]

Course of Treatment: is a series of similar treatments administered to a person over a period of time for a particular health problem. Example: four courses of chemotherapy over the course of two weeks.

Plan of Treatment is a plan that:

- is developed by one or more healthcare practitioners
- deals with one or more of the health problems that a person has and may, in addition, deal with one or more of the health problems that the person is likely to have in the future, given the person's current health condition, and
- provides for the administration to the person of various treatments or courses of treatment in light of the person's current health condition
- Example: Cardiac bypass surgery followed by appropriate medications or nursing care

Community Treatment Plan: is defined in the Mental Health Act and is a "plan that is a required part of a community treatment order" (CPSO, p. 4, 2005).

An Emergency exists where "the patient is apparently experiencing severe suffering, or is at risk of suffering serious bodily harm if the treatment is not administered promptly" (HCCA, subsection 25(1), 1996).

[1] CPSO, *Consent to Treatment Policy*, 2005, p. 4

2. PROCEDURE

1. Obtaining Consent

Informed consent must be obtained through discussion between the Healthcare Practitioner (HP) proposing the treatment and the patient, or the patient's substitute decision maker (SDM), in which the HP provides all the necessary information to the patient regarding the proposed treatment and answers the patient's questions about the particular proposed plan of treatment.

2. Documentation of Consent

The process for obtaining consent and the documentation of the process (written verification) are different. A signed consent form does not constitute consent; rather the form is evidence that a discussion about a proposed treatment took place. Regulated healthcare practitioners should be familiar with their College requirements for documenting those treatments for which they obtain consent. Not all treatments require that a consent form be completed however; QHC requires that the HP proposing the treatment to have the QHC Consent to Treatment form completed by the patient or SDM for:

- all surgical procedures
- all procedures requiring anaesthesia and intravenous sedation that will significantly affect the patient's level of consciousness
- high risk invasive procedures
- transfusion of blood and blood products/components
- treatment or procedures that will result in the ablation of bodily function, and
- at any time when deemed necessary by the HP

The signed Consent to Treatment form provides an efficient means of communicating to other healthcare practitioners who are accountable for ensuring informed consent, that a discussion about a proposed treatment took place.

A signed consent form includes the following principles:

- The patient who is undergoing the treatment and who is capable with respect to that treatment must sign the form
- If the patient is not capable with respect to treatment, the patient's SDM must sign the form
    - If the SDM cannot be located and an emergency treatment condition exists the HP directing the treatment plan signs the *Emergency Treatment Without Consent* form
- All relevant section(s) of the consent form must be completed
- Abbreviations must not be used on the consent form when describing procedures

Documentation of Consent Discussion By Health Care Provider Proposing Treatment

In addition to having the patient or SDM sign the written consent form, it is the responsibility of the HP proposing the treatment to document specifics about the consent discussion in the patient's health record including:

- The HP's opinion about patient's capacity to consent to the specific treatment
- When the discussion occurred
- Who was present during the discussion
- The name of the HP obtaining consent
- Details about the information provided to the patient/SDM and any concerns or questions expressed by the patient/SDM
- Who provided the consent to treatment
- If information sheets are utilized, evidence of the patient/SDM receiving a copy

Documentation of Informed Consent Confirmation

Additionally, HPs who by their standards of practice are required to ensure informed consent occurred are to document the confirmation of informed consent in the patient's chart. This includes documenting that the HP has verified with the patient or SDM that they signed the consent form and whether they have any questions or concerns regarding their understanding of the proposed treatment/procedure. If the patient or SDM does have questions or concerns the HP must ensure those questions or concerns are addressed prior to the procedure or treatment. These actions must also be documented in the patient's chart.

3. Who Obtains the Written Consent?

The treating HP is responsible for ensuring that the patient or his/her SDM has given an informed consent to treatment. This is done by whoever is proposing the treatment and is in the best position to explain the risks, benefits and alternatives to the patient and respond to related questions. This may be done by a physician, therapist, nurse or technician. It is important that the consent form be signed by the patient or SDM at the time the discussion of the proposed treatment takes place.

4. Assessing Capacity

Although there is a legal presumption that all patients have capacity, the capacity of a patient to consent to treatment can change at any time (College of Nurses of Ontario, 2009; College of Physicians and Surgeons of Ontario, 2005). Assessing capacity is the responsibility of the HP proposing the treatment. If a patient is found to be incapable of consenting to treatment, the patient's SDM may give consent on the patient's behalf.

5. When is Written Consent Required?

Written consent must be obtained by the HP proposing the treatment for:

A. All surgical procedures

B. Designated operations, procedures and treatments performed in any area of the hospital that involve:
    i. Any high risk invasive procedure;
    ii. Interventional radiology;
    iii. Invasive modalities for pain management; and;
    iv. Any cardiac exercise stress testing.

C. Operations, procedures and treatments that:
    v. Are likely to be more than mildly painful;
    vi. Involve appreciable risk;
    vii. Will result in loss of a bodily function;
    viii. Involves the use of analgesic, narcotic, or anaesthetic agents that will significantly affect the patient's level of consciousness during the treatment (CMPA, 1996).

D. All non-operative procedures carrying a degree of risk for harm to the patient such as the administration of chemotherapy, blood and/or blood products and diagnostic testing including HIV testing.

***If there is any doubt that a written consent is required, obtain a written consent**.

6. Age of Consent

There is no minimum age of consent to treatment in Ontario.[2] If, in the judgment of the treating health care professional, the patient has the capacity to consent (i.e. is mature enough to understand the nature and consequences of the treatment decision), the patient can give her/his own consent.

A minor who is a ward of a Children's Aid Society or for whom a guardian has been appointed has all the rights a child would have if living with her/his parents. The organization or guardian having custody of the child has the same right, duty and responsibility as a parent. Therefore, a minor in such circumstances may consent to treatment just as any other minor might do.

Note: The younger the patient is and the more significant the procedure, the greater the care that should be taken to evaluate capacity. This may involve obtaining a second opinion from another physician and documentation of the assessment by the second physician.

[2] Note that there is an exception in the Hospital Management regulation of the Public Hospitals Act: s. 27 prohibits performing surgery to sterilize a person under 16 unless the attending physician is of the opinion that it is medically necessary to protect the physical health of the patient.

7. Patient's Questions or Concerns

If the patient has questions or concerns about the planned treatment, the attending physician or other HP who is proposing the procedure or treatment must be notified immediately and the treatment delayed until the patient's questions or concerns are addressed.

8. Language Barriers

If a patient or SDM is unable to understand or communicate clearly with the HP due to a language barrier, attempts must be made to communicate with the patient or SDM in their preferred language. In such cases the HP should arrange qualified interpretation through a telephonic (over the phone) or face-to-face interpreter (See *QHC policy 2.3.5 Accessibility – Request for Sign Language and Interpreting Services*). Whenever possible, the use of other staff or family members as interpreters should be avoided.

9. Duration of the Consent

The Health Care Consent Act does not stipulate a time frame for the validity of a signed consent form. Consent is valid until:

- The treatment consented to is performed
- The patient's condition changed
- The patient withdraws the consent
- Further risks become known, or alternative treatments become available.

Unless the patient explicitly states that his/her consent is being withdrawn, there is a presumption that the patient's consent is still in force and that there is no need to explicitly verify it. However, it is strongly recommended that anyone performing a procedure should reconfirm that the patient has had the procedure fully explained and had an opportunity to ask questions if more than one month has passed and to document the process with a new written consent form if more than one year has passed.

10. Telephone/Fax/E-mail Consent

Fax and e-mail consents are acceptable; however, efforts to obtain consent in person are preferable. If consent is to be obtained through fax/e-mail it must be included in the patient's health record. In every case where the consent relied upon is transmitted by fax or e-mail, the person requesting the consent form must ask that the original signed consent form be sent by regular mail as a follow-up. The original signed consent form must also be filed in the patient's health record.

The same requirements for informed consent exist for consent obtained through telephone contact, fax or e-mail. If a patient is unable to sign his/her consent form, telephone consent from the SDM may be obtained. A witness (2nd Party) to the telephone consent discussion must co-sign the form. Appropriate identification of the SDM over the phone is accomplished through verbal confirmation by the HP obtaining consent and an additional witness that the person providing consent is the known SDM.

11. Substitute Decision Maker
Refer to *Appendix A* for hierarchy of substitute decision maker (SDM).

Exception to Hierarchy: A person may act as a SDM even if another person higher in the hierarchy is available if the potential SDM believes that the higher ranked person would not object to him or her making the decision.
Example: A daughter consenting to her incapable mother's treatment while the patient's husband is at home.

If two equally ranked people disagree about whether to give or refuse consent, the Public Guardian & Trustee may elect to make the decision. Prior to this, contact the unit manager/designate and/or a representative from the QHC Bioethics Committee.

12. Witnessing and Third Party Signatures
There is no legal or professional standard (CNO, CPSO) requiring a consent form to be witnessed. The patient after providing informed consent is required to sign the acknowledgement section of the consent to treatment form. This indicates that a discussion about a proposed treatment took place. In addition to this, for surgical and invasive procedures, the proposing HP should document the consent process in the patient's health record.

If the patient or his/her substitute decision-maker is unable to physically sign the form, due to a physical disability then the signature of a second party is required on the consent form. The patient, if capable, should indicate verbal agreement to the treatment in the presence of two witnesses. The witnesses should sign the consent form and a notation should be made on the form to indicate that the form was read to the patient and the reason why the patient was unable to sign. If the patient is illiterate and unable to sign their name they may make a mark on the consent form that is recognized as the patient's own identifier in place of a signature.

13. Patient who is Developmentally Challenged
Patients who are developmentally challenged are often capable of making decisions in some areas but not in others. Consult with family and other care providers (i.e. long term care providers) before assessing the patient's capacity.

14. Special Needs
When giving a patient information about a treatment, the HP shall use a means of communication that takes the patient's age, education, language, culture and special needs into account. It is a critical element of the consent process that the parties understand each other fully. Therefore, it may be necessary or desirable to employ the assistance of an interpreter. Refer to Accessibility Policy # 2.1.5 to provide interpreter service. The person providing interpretation or special communication assistance must declare that they accurately interpreted both the information shared by the HP to the patient and the patient's responses to the HP before the treatment is initiated.

15. Patient has Received Medication that Affects the Central Nervous System

The patient can consent to the proposed treatment providing that he/she exhibits no decrease in level of consciousness, is not confused, or is not disoriented as a result of the medication or agents.

If any of the above is present, treatment must be postponed until the patient is deemed capable to consent with respect to the proposed treatment, unless delay would precipitate emergency conditions.

16. Withdrawing Consent

The principles of consent also include the patient's right to withdraw consent. The patient or SDM, in the case of an incapable patient, has the right to withdraw consent at any time. The withdrawal of consent should be noted in the patient's health record and on the consent form. No treatment may be administered once the consent has been withdrawn.

17. Cultural Considerations

Patients come from a variety of cultural backgrounds. It is a challenge applying cultural and legal standards expected by the Canadian system and medical profession to people who may not share the same belief structure. The HP must respect the cultural practices of the patient while meeting legal and professional obligations. Effective communication is critical and highlights the importance of the need to provide full disclosure and obtain informed consent.

18. Prior Capable Wishes and Advance Directives

Prior Capable Wishes are instructions regarding the type of treatments or procedures that a capable person who is at least 16 years of age would or would not want to receive in various situations. These wishes may be expressed orally or in writing or in any other medium (e.g. video). For the purposes of this policy, a document or recording expressing a patient's prior capable wishes is called an Advanced Directive. If available, a copy of the Advance Directive should be placed in the patients' chart. If a situation arises and the patient is deemed incapable and the SDM is directing the care in a way that is in contravention of the Advance Directive the following resources are available:

- The manager of the area involved
- The Director responsible for the program involved
- A consult with the Bioethics Committee (x 2934)

*Note: The Prior Capable Wishes expressed through an Advance Directive are only binding on a Substitute Decision Maker if the person is 16 years of age or older. If a person under the age of 16 years has purported to make an advance directive regarding their care while capable and becomes incapable, the person's advance directive does not hold the same legal force as the wishes of a patient 16 years of age and older, and the SDM is called upon to give or refuse consent in accordance with the principles in section 21 of the HCCA. See *Appendix A* in regards to the criteria the SDM is to take into consideration when determining to give or refuse consent.

19. Blood and Blood Product Administration

Refer to: *QHC Policy 3.1.1 Blood-Blood/Blood Product Utilization Guidelines*
QHC Policy 3.1.2 Blood-Blood/Blood Product Verification, Request and Monitoring
Appendix B Blood and Blood Products Requiring Written Consent
Appendix D Consent to Blood Transfusion/Manufactured Blood Products

Informed consent requirements apply specifically to the administration of blood or blood products. Routine hospital admission consent forms do not fulfill this requirement (Health Canada, 2004). Each patient undergoing a transfusion of blood or blood products must indicate his/her consent or refusal to undergo transfusion.

The ultimate responsibility for obtaining informed consent lies with the HP proposing the treatment. As per the *Krever Commission Interim Report* it is strongly recommended that the treating physician obtain the informed consent of the patient to the administration of blood and blood products in such a way that they will be informed of the risks and benefits of, and alternatives to, allogeneic blood transfusion. The Consent to Blood Transfusion / Manufactured Blood Products form *(see Appendix D)* is to be completed and signed by the patient or SDM.

Surgical Procedures
If a Type and Screen (TS) is ordered for any surgical procedure this indicates that there is the potential that blood and/or blood products may be administered during the surgical procedure. Therefore the patient should be informed and specifically consent to blood transfusions (except in emergency cases when the patient is unable to consent). The Consent to Blood Transfusion / Manufactured Blood Products form is to be completed and signed by the patient or SDM.

If during the course of a surgical procedure blood or blood products are administered the patient must be informed that they did in fact receive these products. This is part of the complete informed consent process.

Ongoing Transfusion Therapy – A patient for whom regular transfusion therapy forms a part of the treatment plan may give his/her consent to transfusion therapy and this consent shall be valid for the duration of the ongoing transfusion therapy until a calendar year passes and/or the treatment plan is altered.

20. Jehovah's Witnesses

The use of blood or blood products as a therapeutic treatment contravenes the belief structure of Jehovah's Witnesses, therefore healthcare practitioners have a responsibility to respect the decision of patients not to receive blood or blood products and to discuss and document alternative treatment options with them.

21. Emergency Conditions

An emergency exists if the person for whom treatment is proposed:

- Is apparently experiencing severe suffering, or
- Is at risk of sustaining bodily harm if the treatment is not administered promptly

22. Emergency Treatment Without Consent

22.1 Incapable Patient

An incapable person may be treated without consent in an emergency situation when a SDM cannot be located in time.

22.2 Communication Barrier

Emergency treatment without consent may be provided to a person who is apparently capable but the communication needed to get consent or refusal cannot take place in a timely fashion because of a language barrier or disability. Steps that are reasonable in the circumstances must be taken to find a way for the communication to take place and there must be no reason to believe that the person does not want the treatment.

22.3 Prior Wishes

A Health Practitioner cannot administer treatment if he or she is aware that the person, while capable, expressed a wish not to have the proposed treatment.

22.4 Continuing Efforts to Get Consent

Where treatment is begun in one of the above situations, the health practitioner must ensure that all reasonable efforts are continued to find a SDM or a means of communication. Once the emergency phase has ceased all treatments including administration of blood and blood products must be explained to the patient, if capable of receiving this information, or the appropriate SDM.

Emergency treatment may only be continued without consent for as long as it is reasonably necessary to locate the SDM for the incapable person and obtain consent to, or refusal of, the continuation of treatment.

APPENDICES AND REFERENCES

Appendices: Appendix A − Substitute Decision-Maker (SDM)
Appendix B − Blood and Blood Products Requiring Written Consent
Appendix C − Consent to Treatment Form
Appendix D − Consent to Blood Transfusion/Manufactured Blood Products

References:

Canadian Medical Protective Association: Consent a Guide for Canadian Physicians 4th Edition, 2006.

College of Nurses of Ontario. (2009). *Practice Guideline, Consent*. Toronto, Ontario: College of Nurses of Ontario

College of Physician and Surgeons of Ontario. (2005). *CPSP Policy Statement, Consent to Medical Treatment.*

Health Care Consent Act, 1996. (1996). Ontario Regulation 856/93. Retrieved May 4, 2009. Available at: http://e-laws.gov.on.ca

Grainger, B., Margolese, E. (1997). Legal and ethical considerations in blood transfusion. *Canadian Medical Association Journal*. Retrieved March 4, 2010from:http://www.collectionscanada.gc.ca/eppp-archive/100/201/300/cdn_medical_association/cmaj/vol-156/issue-11/blood/backgrnd/grainger.htm

Health Canada. (2004). *Commission of Inquiry on the Blood System in Canada (Krever Commission).* Available at:
http://www.hc-sc.gc.ca/ahc-asc/activit/com/krever-eng.php

QHC Resource Manual – Blood and Blood Product Administration

Substitute Decisions Act, 1992.
https://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_92s30_e.htm

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Related Policies and/or Legislation
Health Care Consent Act, 1996
Family Law Act, 1990.
Substitute Decisions Act, 1992.
QHC (2.3.5) Accessibility – Request for Sign Language and Interpreting Services
QHC (3.1.1) Blood-Blood/Blood Product Utilization Guidelines
QHC (3.1.2) Blood-Blood/Blood Product Verification, Request and Monitoring