

	<p>POLICY</p> <p>Number: 7311-50-002 Title: Consent/Informed Consent</p>
<p>Authorization</p> <p><input type="checkbox"/> President and CEO <input checked="" type="checkbox"/> Vice President, Finance and Corporate Services</p>	<p>Source: Director, Practitioner Staff Affairs and SHR Legal Counsel Cross Index: Date Approved: November 22, 2007 Date Revised: March 4, 2015 Date Effective: May 29, 2015 Date Reaffirmed: Scope: SHR</p>

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OVERVIEW

Consent is a process which involves effective communication and a "working relationship of trust" between the Most Responsible Health Practitioner (MRHP) and the patient. The relationship is mutual/reciprocal and takes into account the patient's needs and expectations, while recognizing the MRHP's responsibility to respond and explain.

Where a patient lacks capacity, the MRHP identifies the correct individual to engage in the consent process (substitute decision-maker, proxy or other individual legally appointed as identified in an advanced healthcare directive).

The components of consent are:

Communication: Mutual communication of relevant information to and from the patient.

Capacity: The patient's ability to understand information relevant to making a decision.

Voluntariness: The patient's right to come to a decision freely, without force, coercion, or manipulation.

DEFINITIONS

Appreciable Risk means a risk that a reasonable person in the patient's position would likely attach significance (to the risk or cluster of risks) in determining whether or not to undergo the proposed treatment/procedure; includes "a mere possibility" if it carries with it serious potential consequences such as paralysis or death.

Consent means an autonomous authorization from the patient/Substitute Decision Maker (SDM) for a physician/treatment provider to carry out a treatment/procedure.

There are Two Types of Consent

- 1. Expressed Consent:** means direct, explicit agreement to undergo a treatment/procedure(s), given either verbally or in writing.
- 2. Non-Verbal/Implied Consent** means the patient indicates a willingness to undergo a certain procedure or treatment by his or her behavior/conduct.

Emergency means instances where a patient is experiencing severe suffering (that can only be relieved through prompt treatment) or is at risk of sustaining serious bodily harm if treatment is not administered promptly.

Informed Consent is a patient's authorization to carry out a treatment, surgical procedure, or diagnostic intervention after he or she is provided the information/facts needed to make an informed decision.

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

Most Responsible Health Practitioner (MRHP) means the Health Practitioner who has the responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by Saskatoon Health Region (SHR) to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

Substitute Decision Maker (SDM) means a person who, pursuant to *The Health Care Directives and Substitute Decision Makers Act*, is entitled to make health care decisions on behalf of the subject individual (see Appendix A).

Treatment/Procedure/Intervention means anything that is done for a therapeutic, preventive or palliative purpose; investigative procedure(s); or series of treatments/procedures planned to manage a clinical condition.

1. PURPOSE

The purpose of this policy is to establish SHR's position and requirements regarding consent/informed consent.

2. PRINCIPLES

- 2.1** A relationship based on openness, trust and good communication enables the MRHP to address the patient's individual needs.
- 2.2** Patients shall be given relevant information, including the appreciable risks and consequences of each option, including no treatment.
- 2.3** The process of informed consent provides patients with the opportunity to ask questions (ideally in person) such that they understand the recommended treatment/procedure, and understand the risks, benefits, and alternative treatment procedures, if any, as well as the risk of forgoing the recommended treatment.
- 2.4** A signed consent form is not the consent itself but may be evidence of consent.

3. POLICY

3.1 All consent shall be informed consent.

3.2 A valid expressed consent (written or verbal) shall be obtained from the patient/client/ SDM before any treatment/procedure/intervention.

3.2.1 Consent is implied when patients/clients attend a SHR facility to have routine lab work, non-invasive diagnostic testing, and/or a routine IV start.

Exception:

Testing for blood borne Pathogen or HIV testing is not considered routine, however, specific **verbal** consent is sufficient, but must be documented.

3.3 Criteria for a Valid Consent¹

For consent to be valid, all of the following criteria shall be met (except in emergency situations):

3.3.1 The patient/SDM shall be legally competent and mentally capable to give consent to a treatment/procedure.

3.3.2 The consent shall be given voluntarily, and not obtained through undue inducement, pressure or with an element of force, fraud, deceit, duress or coercion.

3.3.3 The patient/SDM shall receive communication of information from the MRHP including:

- the nature and purpose of the proposed treatment/procedure;
- the appreciable risks and benefits of the proposed treatment/procedure;
- reasonable alternatives to treatment/procedure if any exist, together with the risks and benefits of the alternatives;
- the impact of treatment/procedure on the patient's lifestyle economic considerations which may affect the patient giving or refusing consent;
- the consequences of refusing treatment/procedure; and
- who is to perform the treatment/procedure.

3.3.4 The consent shall be specific both to the treatment or procedure being performed and, to the persons who are to perform the treatment or procedure.

3.3.5 The patient/SDM shall have an opportunity to ask questions and to receive understandable answers.

¹ Rozovsky, Lorne E. and Fay A. (1990). The Canadian Law of Consent to Treatment. Butterworths: Toronto.

3.4 Written Consent

3.4.1 Written consent must satisfy all of the elements of consent including: capacity, non-coercion, voluntariness, disclosure and understanding. The consent must include the opportunity to ask questions and have them answered so that one understands.

3.4.2 **Written Consent** is required for the following:

- Admission;
- All surgical procedures;
- Diagnostic and therapeutic procedures involving an intervention
Removal and donation of body tissues (routine lab work is an exception see 3.2.1);
- Autopsy (in coroner's cases, no autopsy shall be performed unless and until authorized by the coroner);
- Use of treatment/procedure or drugs under investigation;
- Administration of anesthetic agents that are expected to affect the patient's level of consciousness or mobility during or following the treatment/procedure;
- All procedures which involve appreciable risk to the patient. If there is any doubt about the need for a written consent, the MRHP shall obtain written consent;
- Course of treatment decisions in ICU.

3.4.3 Faxed written consents are acceptable due to distance and other special circumstances.

3.4.4 **Exceptions to Written Consent**

Where written consent is required and is not obtainable, verbal consent (including telephone consent) is acceptable due to such obstacles as distance and physical inability. Verbal consent shall be documented at the time consent is obtained.

3.5 Verbal Consent

3.5.1 Verbal consent is acceptable in all instances where written consent is not obtainable (see section 3.4 above). Verbal consent shall be obtained using the consent process (see procedure).

3.5.2 Verbal consent shall be documented including the information referred to in 3.3.3.

3.5.3 The MRHP will communicate information as per 3.3.3 above.

3.6 Emergency Situations

3.6.1 In emergency situations where the patient cannot give consent, the substituted consent of two healthcare providers is required.

3.6.2 The treatment/procedure can proceed if the following criteria are met:

- there is a serious threat to life or wellbeing of the patient which requires immediate treatment/procedure;

- the situation is such that there is no time to complete the consent process without jeopardizing the life or health of the patient;
- there is no knowledge that the patient would have objected to the treatment/procedure (i.e.: advance healthcare directive); and
- all treatment/procedure(s) provided shall be that which are required to alleviate the life or health threatening condition;
- a second Health Care Practitioner agrees with the need for the treatment/procedure.

3.6.3 Substituted consent shall be documented.

3.6.4 It is the responsibility of the MRHP to record his/her opinion that the consent could not be obtained, that the treatment/procedure was necessary and could not be delayed, to detail the nature of the treatment/procedure, and to obtain the concurring written opinion of another HCP.

3.7 Authority to Obtain Consent

3.7.1 The authority to obtain consent rests with the MRHP who performs the treatment/procedure.

3.7.2 The responsibility of obtaining consent **cannot** be delegated to another Health Practitioner (nursing staff, technician, technologist, etc.) for treatment/ procedure to be performed by the MRHP.

3.7.3 Obtaining consent cannot be delegated to anyone who does not possess the knowledge necessary to adequately present all the pertinent risks, benefits and alternative treatment/procedure(s). The MRHP can delegate all or part of the process to a knowledgeable individual to obtain informed consent but the responsibility to ensure consent is obtained lies with the MRHP.

3.8 Authority to Give Consent

3.8.1 Patients may give consent regardless of age to their own treatment/ procedure when they are able to understand and appreciate the nature of their illness, the options available for treatment/procedure(s), and the risks and benefits associated with each treatment/procedure option or refusing the recommended treatment/procedure.

3.8.2 A parent or legal guardian will give consent for a child who is not considered a mature minor.

3.8.2.1 Where one of the parents has sole legal custody of the child, the parent who has sole legal custody, regardless of the residence of the child, is authorized to give consent.

3.8.2.2 Where there is joint custody either parent is authorized to give consent.

3.8.2.3 Where there is no parent or guardian, the person having physical custody may in exceptional circumstances sign a consent on behalf of the patient.

3.8.3 **Mature Minors**

3.8.3.1 If the child is assessed and is deemed capable of consenting to treatment he/she is allowed to make all treatment/procedure decisions.

3.8.3.2 Children who are not yet capable should, to the extent that is reasonable, be included in decision making and informed about decisions that have been made for them. Discussions should be at an age appropriate level.

3.8.3.3 Where a child is committed to the Minister of Social Services under the Child and Family Services Act, the consent may be given only by the Minister, or his/her designate, unless the child is a mature minor.

3.8.4 **Advanced Care Directives (ACD)**

3.8.4.1 A Patient with a valid ACD (Living Will) can provide consent for future healthcare decisions (see SHR Policy Advanced Care Directives).

3.9 **Withdrawal of Consent**

3.9.1 A patient/SDM may, at any time, withdraw his/her consent for a specific treatment/procedure.

3.9.2 The MRHP shall advise the patient/ SDM regarding the consequences and the risks of not proceeding with the advised treatment/procedure.

3.9.3 The MRHP shall ensure the patient/SDM understands all the repercussions of withdrawing consent.

3.9.4 The consultation and the patient's/ SDM's withdrawal of consent shall be documented on the patient's health record. Specifically, the MRHP will note the patient's withdrawal of consent on the consent form. Other documentation shall include:

- a summary of the information that was provided to the patient about the treatment/procedure;
- the patient's/SDM's reasons for withdrawing consent, if known; and
- the expected outcomes of not receiving the treatment/ procedure(s).

3.9.5 The patient/SDM may provide consent to treatment/procedure again at any time following an informed consent discussion.

4. **ROLES AND RESPONSIBILITIES**

4.1 **Most Responsible Health Practitioner**

4.1.1 Determines capacity

4.1.2 Determines appropriate form of consent

4.1.3 Communicates information

4.1.4 Documents consent

5. POLICY MANAGEMENT

The management of this policy including policy education, monitoring, implementation and amendment is the responsibility of Director, Practitioner Affairs and SHR Legal Counsel.

6. NON-COMPLIANCE/BREACH

Non-compliance with this policy will result in a review of the incident. A review for non-compliance may result in disciplinary action, up to and including termination of employment and/or privileges.

7. REFERENCES

The Adult Guardianship and Co-decision-making Act, Saskatchewan
The Children's Law Act, 1997 (section 48-blood tests)
The Healthcare Directives and Substitute Healthcare Decision Makers Act, Saskatchewan
The Healthcare Directives and Substitute Healthcare Decision Makers Regulations, Saskatchewan
The Health Information Protection Act, Saskatchewan
The Hospital Standards Act, Saskatchewan
The Hospital Standards Regulations, Saskatchewan
The Human Tissue Gift Act, Saskatchewan
The Mental Health Services Act, Saskatchewan
SHR SDM Decision Tree

PROCEDURE	
Number: 7311-50-002 Title: Consent/Informed Consent	
Authorization <input type="checkbox"/> President and CEO <input checked="" type="checkbox"/> Vice President, Finance and Corporate Services	Source: Director, Practitioner Staff Affairs and SHR Legal Counsel Cross Index: Date Approved: November 22, 2007 Date Revised: March 4, 2015 Date Effective: May 29, 2015 Date Reaffirmed: Scope: SHR

Consent Process means a discussion or series of discussions and interactions between the Most Responsible Health Practitioner (MRHP) and the patient/SDM including:

- i) the determination of capacity,
- ii) the provision of relevant information,
- iii) the verification of understanding,
- iv) the decision-making, and
- v) the documentation of the consent process and outcome.

1. PURPOSE

The purpose of this procedure is to establish the process for obtaining consent/informed consent.

2. PRINCIPLE

Consent is a process involving a discussion or series of discussions and interactions between the MRHP and the patient/SDM.

3. PROCEDURE

3.1 The Determination of Capacity

3.1.1 Assessing Capacity

The MRHP is responsible for assessing the patient's capacity to make the decision.

There are several criteria to determine if a patient is capable of consenting to treatment. In determining capacity to treatment the MRHP takes steps to determine whether the patient understands and is able to communicate regarding the details, these details include:

- the condition for which the specific treatment/procedure is proposed;
- the nature and purpose of the specific treatment/procedure;
- the risks and benefits involved in undergoing the specific treatment/procedure; and the risks and benefits involved in not undergoing the specific treatment/procedure;
- the risks and benefits of any alternative treatments/procedures; and
- the risk of not undertaking any treatment or procedure (doing nothing).

3.1.2 **Assessing Mental Capacity**¹

The MRHP will also consider whether the patient suffers from a mental disorder which affects the patient's ability to appreciate the consequences of making the treatment/procedure decision.

The following may be considered while assessing mental capacity:

- Presence or absence of consciousness.
- Severe pain which compromises the ability of the patient to think or to articulate.
- Ingestion of alcohol and / or drugs to the point that the patient cannot respond to direct questions, cannot supply pertinent information and slips in and out of a drug-alcohol stupor.
- Presence or absence of lucidity.
- Presence or absence of coherency.
- Diagnosed mental disability, such as severe organic brain syndrome, advanced stages of Alzheimer's disease, or severe mental retardation.
- Traumatic injury, illness, or episodes which might have the effect of significantly modifying the individual's ability to think.
- Administration of pain-killing medications which do not simply "blunt" the effects of pain, but which might alter the individual's thought process.

3.1.3 **Patients who lack capacity to make decisions**

3.1.3.1 A patient is presumed competent and to have capacity to make treatment/procedure decisions unless found by his/her MRHP to be not competent to consent to treatment/procedure.

3.1.3.2 If the patient is not capable of making a decision the MRHP shall document the circumstances in the patient's health record and consent shall be sought from the SDM.

3.1.3.3 Where the MRHP has evidence to show a patient is incapable to consent to treatment, contact the SDM and/or request a psychiatric consultation where appropriate.

3.2 **The Provision of Relevant Information**

3.2.1 Provide the patient with the following information to understand the proposed treatment/procedure during the consent process:

- the purpose of a proposed treatment/procedure;
- the details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief;
- how the patient should prepare for the treatment/procedure;
- the details of what the patient might experience during or after the treatment/procedure, including common and serious side effects;
- the benefits of the treatment/ procedure and what will happen if not treated; and
- the options and alternatives to treatment/procedure, including benefits and limitations of each and if the treatment/procedure is experimental.

¹ Canadian Law of Consent to Treatment, page 8

- 3.2.2 A supplemental explanation document/video for a particular treatment/procedure is an acceptable tool to assist the MRHP in disclosing the information required for a patient to give an informed consent.
- 3.2.3 Using supplemental documentation/videos are only supplements to the informed consent process and do not replace the responsibility for obtaining informed consent to treatment/procedures.

3.3 Verification of Understanding

- 3.3.1 Provide the patient with the opportunity to ask questions and provide understandable answers.
- 3.3.2 Prior to the procedure, the MRHP asks the patient/SDM if he/she has a clear understanding of the upcoming treatment/procedure. If there is not a clear understanding, the MRHP discusses the procedure with the patient/SDM.

3.4 The Decision-Making

Patient/SDM makes the health care decision.

3.5 Documentation of the Consent Process and Outcome

- 3.5.1 The MRHP ensures appropriate documentation of the consent process on the patient's health record.
- 3.5.2 A written consent for surgical, diagnostic or treatment/procedure may be obtained before admission at a pre-operative or pre-admission consultation. If this is done, the written consent shall be on the health record prior to the treatment/procedure being performed.
- 3.5.3 If either the nature of the treatment/procedure or the associated risks have changed within the period between the date consent was obtained and the performance of the procedure or treatment, a new consent is required.

3.6 Special Circumstances in Obtaining Consent

3.6.1 Telephone/Fax Consents

- 3.6.1.1 Telephone consent should only be obtained when consent is needed immediately (informed consent should be obtained face to face).
- 3.6.1.2 In the case of a treatment/procedure that requires a signed consent form, the form may be faxed to the SDM, the consent discussion held over the telephone and documented in the progress note, and the consent form signed and returned by fax.
- 3.6.1.3 This type of consent is usually used to consult with a SDM. When speaking to the SDM the MRHP should be satisfied that he or she is speaking to the appropriate SDM, and that the SDM is capable of making the treatment/procedure decision.
- 3.6.1.4 The MRHP shall sign the consent form and provide an explanation of why consent by telephone was required.
- 3.6.1.5 The same requirements for telephone consent exist as for informed consent. Therefore, if the person to whom the call was placed is willing and able to make a treatment/procedure decision for the patient, the MRHP shall explain the following:

- the nature of the patient's condition for which treatment/ procedure is proposed;
- the proposed treatment/procedure;
- the appreciable risks and benefits associated with the proposed treatment/procedure;
- any reasonable alternative forms of treatment/procedure along with the risks and benefits of such alternative treatment/ procedure; and
- the consequences of foregoing all treatment/ procedure.

3.6.1.6 The person to whom the call was placed shall be given an opportunity to ask questions regarding the proposed treatment/ procedure.

3.6.2 **Consent for Blind, Deaf, Illiterate and /or those with a Language Barrier**

3.6.2.1 In cases where the patient undergoing treatment/procedure does not speak English and the services of an interpreter are used in obtaining the consent, a signed statement from the interpreter (on the reverse of the form: 100362) is to be completed.

3.6.2.2 In cases where the provision of information is not possible by the usual methods the appropriate information shall still be provided. Implied, expressed or written consent will be obtained in the usual manner.

3.6.2.3 When the person consenting is deaf and not blind, the MRHP may write an explanation and attach the written explanation to the health record.

3.6.2.4 When the person consenting is blind or illiterate, the MRHP will:

- give the explanation;
- read the consent form;
- obtain the consent; and
- acknowledge the consent on the form, stating why the person was unable to sign the form.

3.6.3 **Consent for Testing following a Blood/Body Fluid Exposure**

3.6.3.1 The exposed individual attends the nearest open emergency department (ED) for assessment.

3.6.3.2 The ED Physician conducts an assessment.

- If testing of the exposed individual is required, the ED Physician documents that informed consent for testing was obtained on their personal health record.

3.6.3.3 If it is determined testing is required from the source, the ED physician makes this recommendation to the exposed individual and the source (when the identity of the source is known).

3.6.3.4 The exposed individual advises the Charge Nurse/Clinical Coordinator where the source is located.

- If other than acute care, advise MRHP for that individual.

3.6.3.5 The MRP/MRHP (where the source is located) determines if valid criteria for consent are present (see policy section 3.3).

- If criteria are not present for consent, determine who may give consent on the patient's behalf (see policy section 3.8).
- 3.6.3.6 The MRP/MRHP discusses testing with the source/SDM (see Appendix B).
- If the source/SDM consents to testing, document on the patient/source's health record that informed consent was obtained for testing following an occupational exposure.
 - Follow existing protocols for obtaining testing.
 - If the source/SDM refuses consent, the MRP/MRHP documents the refusal, advises the exposed individual that he/she may personally choose to apply to the court for a testing order² and advises the ED Physician/MRHP of the refusal (as this may influence the treatment plan for the exposed individual).

3.7 Documentation

- 3.7.1 Implied Consent - no specific documentation is required.
- 3.7.2 Expressed Consent - documentation is required
- 3.7.3 Written Consent - is documentation of the consent process, what information has been provided to the person, the response of the person and completion of the appropriate consent form.
- 3.7.4 Supplementary Written/Visual Information - The use of written/visual supplementary information shall also be documented.

4. PROCEDURE MANAGEMENT

The management of this procedure including procedures education, monitoring, implementation and amendment is the responsibility of the Director, Practitioner Affairs and SHR Legal Counsel.

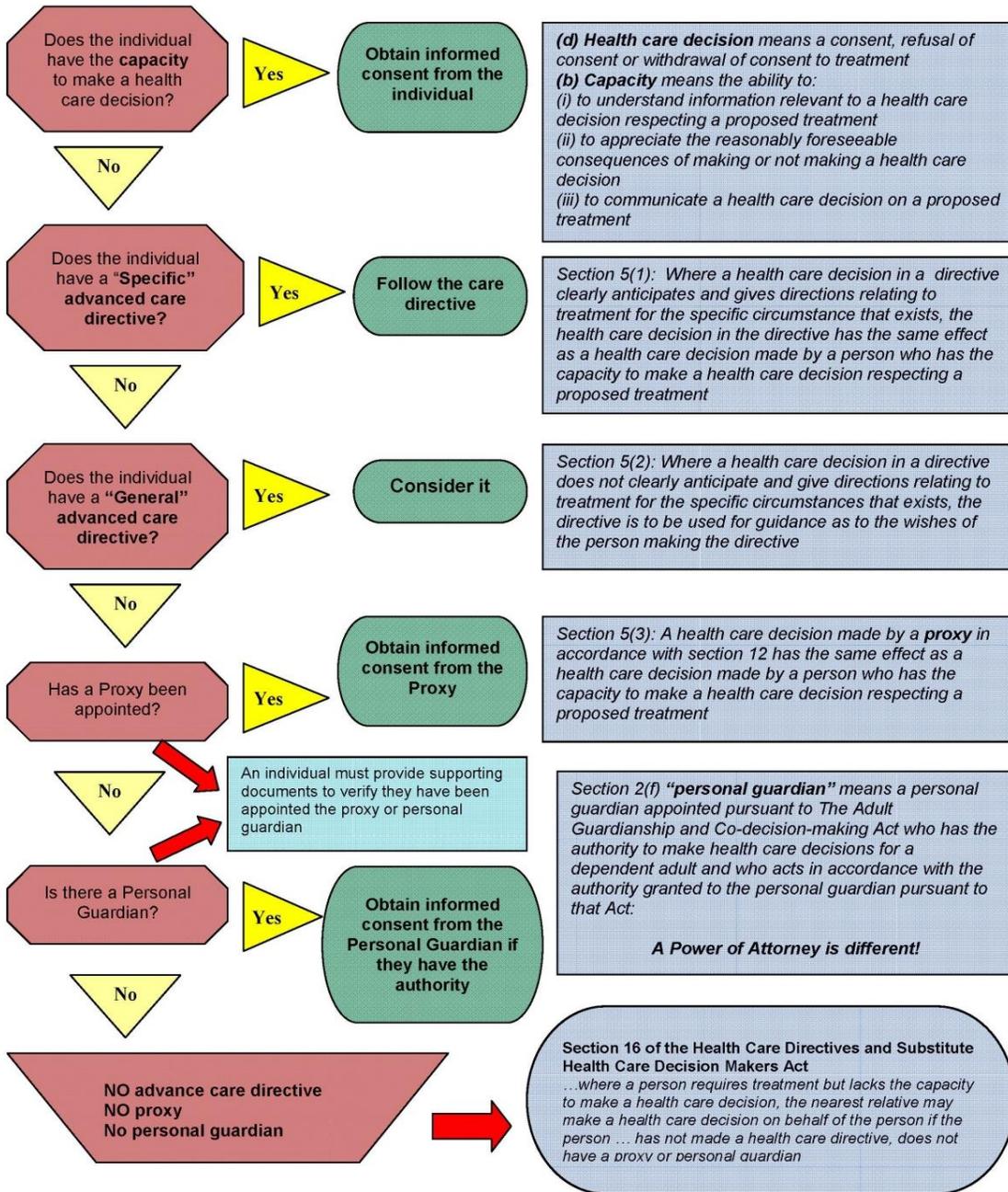
5. NON-COMPLIANCE/BREACH

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6. REFERENCES

Guidelines for the Management of Exposure to Blood and Body Fluids, Appendix 16 (October 2013), Ministry of Health, Saskatchewan

Appendix A - The Health Care Directives and Substitute Health Care Decision Makers Act - A Decision Tree



- Nearest relative (Section 15) in order of sequence:
- (a) Spouse or person with whom the person requiring treatment cohabits and has cohabited as a spouse in a relationship of some permanence
 - (b) Adult son or daughter (beginning with the eldest)
 - (c) Parent or legal custodian
 - (d) Adult brother sister
 - (e) Grandparent
 - (f) Adult grandchildren
 - (g) Adult uncle or aunt
 - (h) Adult nephew or niece
- The relationships listed include adoptive relationships
- Section 16(4): Where there is no nearest relative of where a reasonable attempt to find the nearest relative has been made but the nearest relative cannot be found, and a person requiring treatment lacks the capacity to make a health care decision, a treatment provider may provide treatment in a manner and to the extent that is reasonably necessary and in the best interest of the person without receiving a health care decision from the nearest relative if:
- (a) the treatment provider believes that the proposed treatment is needed; and
 - (b) another treatment provider agrees in writing that the proposed treatment is needed

Consent for Source Patient Testing Following a Blood/Body Fluid Exposure

The source must express an understanding of the following:

- An individual has been exposed to the source's blood/body fluids.
- In order to assist in the care and management of the exposed person, the source will be asked a number of personal questions to assess if there is a risk for hepatitis B, hepatitis C and human immunodeficiency virus (HIV) which causes AIDS.
- A blood test is requested to determine if there is risk for the exposed person.
- The source's attending physician will inform them of the test results and arrange appropriate follow-up.
- Results of the risk assessment and blood test will be sent to the care providers of the exposed person (their attending physician in the Emergency Department, family physician and the Occupational Health/Employee Health Department [if it is health region employee involved in a workplace injury]). These care providers will notify the exposed person of the results so they can obtain necessary treatment and follow-up.
- Identifying information (name, date of birth, health services number) **will not** be documented on the exposed individual's chart, nor with their family physician or the occupational health/employee health department.
- Identifying information **will** be shared with the MHO as a consultant in conducting the risk assessment.
- Physicians are required by *The Public Health Act, 1994* to report information including name, gender, age and risk factors to the MHO of positive tests. Current and past sexual/drug use partners of positive cases will be offered a test.

The source should also be provided with general information for informed consent which includes:

Testing process:

- description of HIV infection, transmission and the window period;
- meaning of positive and negative HIV test results;
- need for further testing based on risks.

Reasons to be tested:

- allows earlier access to services and care;
- helps people live longer, healthier lives without treatment;
- helps people become actively involved in their own care;
- decreases worry about possible infection;
- helps prevent the spread of HIV to others;

Other considerations:

- how the results will impact the client;
- support, assistance, care and treatment options are available and will be offered;
- how to contact the client when results are ready;
- assess risk factors and develop a plan to minimize potential for transmission while awaiting results;
and
- the client has the right to refuse testing.

Consent is verbal, informed, voluntary and documented.

Adopted from the Government of Saskatchewan, Ministry of Health Guidelines for the Management of Exposure to Blood and Body Fluids (October 2013), Appendix 16.