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Communicable Disease Control Manual

Chapter 2: Immunization

Appendix A - Informed Consent for Immunization





Table of Contents

Pu	ırpose and Scope	2
Ele	ements of Informed Consent Process	3
Ge	eneral Definitions	3
Sto	ep By Step Process for Obtaining Informed Consent	4
Ste	p 1: Determine Authority to Provide Informed Consent	4
a)	Adults	4
b)	Parents	4
c)	Mature Minors	5
d)	Foster Parents	6
e)	Other Custodial Caregivers	6
f)	Other Individuals	6
Ste	p 2: Assess Capability to Give Informed Consent	6
a)	Children	7
b)	Adults	7
Ste	p 3: Provide Standard Information	7
Ste	p 4: Confirm Understanding of Standard Information	8
Ste	p 6: Confirm Consent	8
Ste	p 7: Document Consent or Refusal	8
	·	
	•	
	_	10
	·	13
Re	eferences	17
	Eld Ge Ste Ste Ste Ste Ste Ste Ste Ste Ste St	Step 1: Determine Authority to Provide Informed Consent a) Adults

1. Purpose and Scope

Informed consent is an essential pre-condition to providing immunization. It is the professional and legal responsibility of the provider to obtain informed consent prior to immunization. The intent of this informed consent standard of practice is to achieve a more client-centered, consistent, and expeditious approach.

This document describes a process for obtaining consent to immunization, and establishes a standard of practice for obtaining consent for a vaccine or vaccine series. Sections 2 to 6 address consent for immunization of infants, children and capable adults. Section 7 addresses consent for immunization of adults incapable of consenting on their own behalf.

This standard is limited to describing the process of obtaining consent for immunization. Although an assessment of the individual's health is an essential component of the decision to immunize, it is not part of the informed consent process.

The standard of practice outlines:

- Guidelines for assessing authority and capability
- The Standard Information to be provided
- Guidelines to assess understanding
- Documentation of consent or refusal
- How and when specific aspects of the consent process are to be implemented

This document was originally developed by a provincial Informed Consent Working Group and reflects extensive consultation with public health nurses and nurses delivering immunization services in First Nations communities, the office of the Provincial Health Officer, operational and policy managers from the Ministry of Children and Family Development and representatives of the Health Services for Community Living (HSCL). Public health nurses and nurses delivering immunization services in First Nations communities adopted the standard of practice for informed consent for immunization outlined in this document in January 2008.

The standard is congruent with provincial legislation and regulations and standards of professional nursing practice developed by the BC College of Nurses and Midwives (BCCNM).

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2. Elements of Informed Consent Process

- specific to immunization service
- client-centered
- voluntary
- obtained without fraud or misrepresentation
- assesses capability of the person providing consent
- provides Standard Information and time to ask questions and receive answers
- gives person providing consent the right to refuse or revoke consent

3. General Definitions

Note: refer to Section 7 for definitions pertaining to adults assessed as incapable of giving or refusing informed consent.

Adult: an individual 19 years of age or over.

Authority: the right of an individual to make health care decisions (e.g., consent for vaccine series) on their own behalf or for another individual.

Capability: the ability of an individual to understand the Standard Information and that the information applies to the individual being immunized.

Child/Infant/Minor: anyone who is 18 years of age or less.

Client: the individual presenting, or being presented, for immunization services.

Confidentiality: the protection of personal information from disclosure to unauthorized individuals.

Health Care: service performed for a therapeutic, preventative, palliative, cosmetic, or any other purpose related to health.

HealthLinkBC Files: provincial documents that contain information about vaccines.

Informed Consent: the voluntary agreement of an individual, parent/guardian, an individual authorized by the parent/guardian, or a substitute decision maker to immunization after meeting the elements of the informed consent process.

Informed Consent for Vaccine Series: consent for each vaccine intended to be given in a series of 2 or more doses according to the provincial routine schedule as appropriate for age:

- Infant and toddler (0 to 3 years)
- School entry (4 to 6 years)
- School-based (grade 6 and grade 9)
- Adult (19 years of age and older)

These times reflect key contact points with individuals and families.

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Mature Minor: an individual 18 years of age or less who is capable of providing informed consent to their own health care.

Parent/Guardian of a Child: an individual authorized to consent to immunization on behalf of a child (i.e., is authorized to make health care decisions for that child). This can include an individual whom a parent/guardian has authorized to make decisions with respect to the immunization of a child (see <u>Section 4.1 (f)</u>, Other Individuals).

Standard Information: information a reasonable person would need to make an informed decision to consent to immunization (see Section 4.1, Step 3 Provide Standard Information for detailed description).

Substitute Decision Makers (SDM): an individual with the authority to assist or make health care decisions on behalf of an incapable adult (see <u>Section 7.1</u>).

Vaccine: a pathogen-specific preparation of a weakened or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure, or a genetically engineered antigen that upon administration stimulates antibody production or cellular immunity against the specific pathogen. For the purposes of this document, the term "vaccine" is used to include passive immunizing agents such as anti-toxins and immune globulin preparations.

Vaccine Series: Two or more doses of the same vaccine given in sequence at predetermined intervals as needed in order to induce immunity.

4. Step By Step Process for Obtaining Informed Consent

4.1 Initial Visit

The process consists of seven steps:

- **Step 1:** Determine Authority to Provide Informed Consent
- Step 2: Assess Capability to Give Informed Consent
- Step 3: Provide Standard Information
- **Step 4:** Confirm Understanding of Standard Information
- Step 5: Provide Opportunity for Questions
- Step 6: Confirm Consent
- Step 7: Document Consent or Refusal

Step 1: Determine Authority to Provide Informed Consent

a) Adults

Adults give, refuse or revoke consent for their own immunization unless assessed as incapable of doing so, in which case consent must be given on an adult's behalf by a SDM.

b) Parents

Parents have the authority to provide consent for their child except when their decision-making rights have been legally revoked or when their child has consented as a mature minor on their own behalf.

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Adoptive parents have the authority to consent for their child. Prospective adoptive parents have the authority to consent for the child under the signed adoption placement agreement with the Ministry of Children and Family Development.

Defer the consent process if the presenting parent discloses their decision-making rights have been revoked.

If the presenting parent discloses there are differences between parents who both have the authority to consent to their child's immunization, ask "Do you have the authority to consent to this immunization today?". The consent of one parent to immunize a child provides the authority to proceed; however, the presenting parent should be advised to inform the other parent of the immunization. In the absence of contraindications, immunization at the visit is in the best interest of the child. For more information, please see the Questions & Answers resource for immunization providers when there is disagreement between Parents/Guardians who both have the authority to consent to their child's immunization. If required, consult a Program Manager or Risk Management Consultant for further direction in this general circumstance.

Defer and immediately consult a manager/supervisor/Medical Health Officer (MHO) if a presenting parent refuses the urgent administration of post-exposure immunoprophylaxis (e.g., tetanus immune globulin, hepatitis B immune globulin). If **both** parents refuse the urgent administration of post-exposure immunoprophylaxis, consult with the responsible MHO who will assess the urgency of the prophylaxis and discuss the matter with the parents. The final decision to bring the matter to the attention of the Regional Director of Child Protection rests with the MHO.

c) Mature Minors

The Infants Act authorizes a health care provider to provide health care to a minor, an individual 18 years or age or younger, based on consent provided by the minor. This requires that the health care provider is of the opinion that the minor understands the nature and consequences and the reasonably foreseeable benefits and risks of the proposed health care and the health care is in the best interests of the minor.

There is no legal age of consent for health care in BC; instead, a minor's ability to consent depends upon the minor's level of maturity. Mature minor authority takes precedence over parental authority. Mature minors have the authority to give, refuse, or revoke consent for their own immunization as long as the health care provider has assessed the minor's understanding of the details of the immunization, including risk and benefits, and has made reasonable efforts to determine and has concluded that the immunization is in the minor's best interest.

In general, parental consent is sought for students 12 years of age and younger, although there may be extenuating circumstances in which a child of this age may provide their own consent.

For school-based immunization delivery, immunization consent forms and accompanying information are to be sent home with the student, and parents/guardians are encouraged to review the information with their child and involve them in the decision. However, if the student presents without parent/guardian consent, or indicates they wish to make a decision different from that of the parent, it is the immunization provider's professional responsibility to inform them about a mature minor's right to provide or refuse consent on their own behalf. The immunizer should then assess the capability of the minor to provide consent and proceed with the consent process. If the student presents with a consent form that they have signed themselves, the immunizer still has a responsibility to assess the capability of the student to provide consent and confirm the student's understanding of the immunization.

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d) Foster Parents

In accordance with sections 47 and 94 of the *Child, Family and Community Service Act* ^A a foster parent/caregiver has the authority to consent to immunization for a child in their care. It is not necessary to ask the foster parent for proof of authority.

Immunization recommended by immunization providers is regarded as part of routine health care and is implicitly part of the plan of care developed for children in foster care. A plan of care that meets the child's educational, health, and health care needs is developed in accordance with the Ministry of Children and Family Development's Children in Care Service Standards and is referenced in the *Family Care Home Agreement* ^B. The agreement is between the "Director" and "Caregiver(s)", and outlines the caregiver's obligations regarding the care of a child placed in his or her home.

A foster parent may not refuse a foster child's immunization without the authorization of the child's social worker. If you are not satisfied that the social worker has authorized a refusal, bring the matter to the attention of the child's social worker and inform your supervisor.

If a foster parent discloses that the child is in foster care by agreement with the child's parent, the parent may retain the authority to consent. In these circumstances, if there is question about who has authority to consent, contact the child's social worker for clarification.

e) Other Custodial Caregivers

When a child is in the day to day care of an individual other than a parent and that individual makes health care decisions for the child, they may consent to immunization (e.g., grandmother/aunt who is raising the child). It is not necessary to ask the custodial caregiver for proof of authority.

f) Other Individuals

A parent/guardian can give authority to, or revoke authority from, another individual to give consent for their child's immunization. A note must be provided which includes the following information:

- Name of parent/quardian
- Name and birth date of child
- Name of individual given authority to consent
- Date and signature of parent/guardian who has given their authority to other individual

Step 2: Assess Capability to Give Informed Consent

Assess if the person providing consent is capable of giving or refusing informed consent (e.g., assess language, communication methods, hearing, and cognitive abilities).

A Child, Family and Community Service Act, Chapter 46 available at: http://www.bclaws.ca/civix/document/id/complete/statreg/96046_01. Refer to Sections 47 (Effect of interim or temporary custody order) and 94 (Agreements with caregivers)

^B 1.01(f) of the Family Care Home Agreement

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a) Children

Infants/Preschool Children

Infants and young children do not have decision-making capability. They require a person capable of making a decision for them to consent on their behalf. Parents/guardians are usually the decision-makers for their children, unless the parent/guardian lacks decision-making capability.

Mature minors

There is no legal age of consent for health care in BC. Children 18 years of age and under can legally consent or refuse immunization on their own behalf if they demonstrate capability. If the immunizer is not satisfied that a minor has the necessary capability to consent to or refuse an immunization, parental/guardian consent may be sought.

b) Adults

"With appropriate communication and the necessary information and support, most adults can make their own decisions and give informed consent." A Every adult is presumed capable of giving, refusing, or revoking consent for immunization, unless the immunization provider assesses otherwise.

Implicit consent may be obtained from observation of the adult's verbal or nonverbal communication methods that may include gestures, vocalizations, communication boards, or electronic devices. The person accompanying the adult may be able to assist the immunization provider in interpreting the client's communication (e.g., a case worker informs the immunization provider that the adult's behavior means they consent to or refuse immunization).

If the adult is assessed as incapable of giving or refusing informed consent, see Section 7.

Step 3: Provide Standard Information

Before administration of a vaccine or vaccine series, provide Standard Information which includes:

- 1. Consent is obtained for a vaccine or a vaccine series.
- 2. Consent is valid until revoked or as per health authority guidelines.
- 3. Vaccine information contained in HealthLinkBC Files or other provincial resources if applicable:
 - Benefits of vaccination (personal, community)
 - Risk of not getting vaccinated (possibility of getting the disease)
 - Eligibility for the vaccine(s)
 - Common and expected adverse events
 - Possible serious or severe adverse events and their frequency
 - Contraindications
 - Disease(s) being prevented

A Public Guardian and Trustee of British Columbia. Consent to Health Care and the Role of the Public Guardian and Trustee

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Provide adequate time for the person providing consent to review the information.

Defer the consent process and do not proceed with immunization if provision of the Standard Information is refused.

Step 4: Confirm Understanding of Standard Information

Use clinical judgement to confirm the person providing consent understands the Standard Information.

Ways to assess understanding include:

- · Assess non-verbal cues
- Assess questions
- Clarify reasons for silence or refusal to engage in discussion

Defer the consent process and do not proceed with immunization if understanding is not demonstrated. This is an indication that an individual is not capable of giving consent.

Step 5: Provide Opportunity for Questions

Ask the person providing consent if they have any questions and answer to their satisfaction.

Step 6: Confirm Consent

Upon completion of steps 1 to 5, confirm the person providing consent is ready to proceed.

Step 7: Document Consent or Refusal

Document according to health authority guidelines that informed consent has been given or refused, ensuring that the following elements are included in the client record:

- Client identification (name and date of birth)
- Informed consent for immunization obtained or refused
- Name of vaccine or vaccine series
- Date and time consent obtained
- If applicable, the name of the person providing consent and their relationship to the client
- Name of person obtaining informed consent

When mature minor consent or refusal is obtained, documentation must include that the decision was made by the mature minor. This documentation indicates that the provider has:

 Explained the nature and consequences and the reasonably foreseeable benefits and risks of the immunization to the minor.

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• Been satisfied that the minor is capable and understands the nature and consequences and the reasonably foreseeable benefits and risks of the immunization.

Documention of mature minor consent or refusal should include a notation or alert if the child wishes for their immunization record to remain confidential (i.e., not accessible to their parent/guardian). Such a notation/alert in the child's chart indicates that additional steps should be taken to ensure patient confidentiality, and the immunization record should only be released to the child. In this situation, the immunization provider should also include documentation of the child's preferred method of communication and contact information in the event of an adverse event following immunization.

If the provider is not satisfied that a minor has the necessary understanding to consent to or refuse an immunization, the provider should document this and attempt to contact a parent/guardian for consent, so that the child does not miss the opportunity to be immunized.

The person providing consent may provide consent in person (e.g., orally, or by inference through their conduct), in writing, or by telephone.

Any form of written documentation (e.g., consent form or a handwritten note written in pen or pencil) is acceptable provided it includes the following elements:

- Client identification (name and date of birth)
- Statement that the person providing consent has reviewed and understood the Standard Information, has had the opportunity to ask questions, and had their questions answered to their satisfaction.
- Statement of consent or refusal
- Name of vaccine or vaccine series
- Date of consent
- Name and signature of person consenting or refusing
- Relationship of the person consenting to the client being immunized

The following elements must be documented for telephone consent:

- Client identification (name and date of birth)
- Statement of consent or refusal
- Name of vaccine or vaccine series
- Date and time consent obtained
- Name and telephone number of person consenting or refusing
- Relationship of the person consenting to the client being immunized
- Name of person obtaining informed consent

Health Authorities collect personal information under the *Health Authorities Act* and other legislation. The information may be used and disclosed in accordance with the *Freedom of Information and Protection of Privacy Act*.

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Effective Period for Consent:

A consent (provided verbally or in writing) is effective for the length of series consented to, unless consent is revoked.

Healthcare provider judgement should be used to determine if consent needs to be re-obtained (e.g., when years have passed since consent was obtained, unclear if consent was previously obtained according to the standard of practice outlined in Appendix A: Informed Consent for Immunization, change in custodial arrangement).

Refusals:

Refusals, as defined in this section, are reasons provided for declining immunization that are not due to medical contraindications. These are often due to strongly held beliefs or other issues associated with vaccine hesitancy.

A refusal is effective on the day it is given and should not impact the future offer of immunizations. Parents should be informed that all refusals will be reviewed at certain milestones and that they may be contacted in the future. Individual circumstances surrounding a prior refusal to vaccination may change; these may include changes in medical status or in philosophical stance, a change in vaccine recommendations, as well as maturation of an individual to an age where they may consent on their own behalf to vaccines previously refused by a parent/guardian. The possibility that there may have been these types of changes should be considered when making approaches in the future to offer immunization services, with a view to avoiding missed opportunities for vaccination. Refusals of vaccines should be documented as per local health authority guidelines in order to document why a person was not vaccinated at the visit. However, such refusals should not result in programming of immunization registries to suppress the forecasting of the refused vaccine nor prevent providers from offering immunizations at any future encounter.

At a minimum*, refused vaccines should be re-offered at the following milestones:

- Child's 2nd birthday
- Child's 4th birthday
- Child's 10th birthday
- Child's 13th birthday

Such re-offering includes children of parents/guardians who have documented their intention not to vaccinate their child under section 6(e)(ii) of the <u>Vaccination Status Reporting Regulation</u>, B.C. Regulation 146/2019.

Mature minors should be offered the opportunity to consent on their own behalf, without regard to prior parental/guardian refusal (see <u>Mature Minors</u>).

*Note: Influenza vaccine should be offered annually, regardless of previous refusal.

4.2 Subsequent Visits in a Series

Confirm that documentation for consent for vaccine series is in place.

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Assume that consent for vaccine series is in place and proceed with immunization if immunization was provided by a Public Health Nurse or Community Health Nurse working in First Nations Communities in BC. You do **not** have to contact the site where the consent for the vaccine series was obtained **or** confirm the name of the person who gave the consent for the vaccine series. Consent for vaccine series is documented in the original record and does **not** need to be repeated.

Obtain informed consent when the vaccine series was started by a private immunization provider in BC (e.g., physician, pharmacist or other immunization provider or another community provider), or an immunization provider outside of BC.

The client should be assessed at each immunization visit as per <u>Appendix B – Administration of Biological Products</u>, <u>2.3 Client Assessment</u>. New and significant changes to any vaccine (e.g., changes to contraindications, precautions or adverse event) should be discussed with the individual or parent/guardian/representative/SDM who provided the initial informed consent and consent should be reconfirmed. The entire consent process does not need to be repeated.

When informed consent for a vaccine series is in place, another person other than the original consenter can bring the client in for immunization.

Repeat the Standard Information when the person giving consent asks that the information be repeated or requests further information.

5. Checklist for Obtaining Informed Consent for a Vaccine Series

- ☑ Determine authority to provide informed consent.
- Assess capability to give informed consent [i.e., assess if capable of understanding the discussion (e.g., assess the client's methods of communication and hearing, language and cognitive abilities)].
- ☑ Provide Standard Information
 - 1. Consent is obtained for a vaccine or a vaccine series.
 - 2. Consent is valid until revoked or as per health authority guidelines.
 - 3. Vaccine information contained in HealthLinkBC Files or other provincial resources if applicable:
 - Benefits of vaccination (personal, community)
 - Risk of not getting vaccinated (possibility of getting the disease)
 - Eligibility for the vaccine(s)
 - Common and expected adverse events
 - Possible serious or severe adverse events and their frequency
 - Contraindications
 - Disease(s) being prevented
- ☑ Confirm understanding of Standard Information (i.e., use clinical judgment to confirm that the person providing informed consent understands the Standard Information and that the information applies to the person being immunized).
- ☑ Provide opportunity for questions (i.e., ask if there are any questions).
- ☑ **Confirm consent** (i.e., ask the person providing consent if they are ready to proceed).
- ☑ Document consent or refusal.

6. Consent for School-Based Immunization Programs

Clinical Information System Generated Personalized Immunization Consent Forms

Personalized immunization consent forms generated by clinical information systems facilitate immunization based on a client's immunization history by providing the parent/guardian/student with the child's immunization history and identifying what immunizations are outstanding. Best practice for providing immunization service is to administer all vaccine doses for which a recipient is eligible at the time of each visit

Given that personalized immunization consent forms contain personal health information (i.e., the child's immunization history), for those 12 years of age and older, it is prudent to address the consent form to the student, as opposed to the parent/guardian, to align with the privacy rights of mature minors. For students who have previously provided mature minor consent for one or more vaccines and have requested that their immunization record remain confidential, additional strategies should be implemented to ensure the child is aware that the consent form contains a record of their immunization history. This can include:

- the addition of a label or sticker to the envelope which indicates that their immunization record is enclosed
- the health professional having a direct conversation with the child when distributing the consent forms
- the health professional requesting the teacher announce to students when distributing the consent forms that a record of their immunization history is included

Generic School Immunization Consent Forms

PDF versions are available on the BCCDC website at: http://www.bccdc.ca/health-professionals/clinical-resources/immunization/informed-consent.

Decisions regarding the use of personalized consent forms or the printing, distribution, collection, and storage of generic consent forms are to be made by health authorities.

7. Immunization of Adults Assessed as Incapable of Giving or Refusing Informed Consent

The immunization provider always starts with the presumption the adult is capable of giving or refusing consent, and if the provider assesses that the contrary is demonstrated, consent can be obtained from the adult's Substitute Decision Maker (SDM).

If the adult's SDM is not present during the immunization visit, they must provide consent by phone or in advance of the visit by means of written documentation as per <u>Section 4.1, Step 7: Document Consent or Refusal.</u>

Even though an adult presenting for immunization may have consent provided by their SDM, the immunization provider must still seek consent from the presenting adult. For example, when an adult with developmental disabilities presents for immunization with a signed consent form, the immunization provider

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must assess the adult first to determine if they are capable of giving or refusing informed consent A. Being capable of giving or refusing informed consent is limited to the specific vaccine(s) being offered, at the time it is offered. Assess capability at every immunization encounter.

7.1 Definitions

Adult assessed as incapable of giving or refusing informed consent: a person who demonstrates they do not have the capability to understand the Standard Information and that it applies to them at the time of assessment.

Substitute Decision Makers (SDM): an individual with the authority to assist or make health care decisions on behalf of an adult. Substitute Decision Makers are:

- 1. **Personal Guardian:** a 'Committee of the Person' (pronounced Kom-i-tay) is appointed by the court to be a personal guardian of an adult who is declared under the *Patients Property Act* to be:
 - Incapable of managing himself or herself, or
 - Incapable of managing himself or herself and his or her affairs.

A Committee of the Person is responsible for making personal and health care decisions for an adult who is declared to be incapable of managing himself or herself.

- 2. **Representative**: a person named by an adult in a representation agreement to help the adult make health care decisions or to make health care decisions on behalf of the adult.
- 3. **Temporary Substitute Decision Maker (TSDM):** a person chosen by a health care provider to make health care decisions, in the prescribed order and who is available and qualifies:
 - Spouse
 - Child
 - Parent
 - Brother or sister
 - Grandparent
 - Grandchild
 - Anyone else related by birth or adoption to the adult
 - A close friend
 - A person immediately related to the adult by marriage
 - a) To qualify to give, refuse, or revoke substitute consent to health care for an adult, the TSDM must:
 - Be at least 19 years of age,
 - Have been in contact with the adult during the preceding 12 months,
 - Have no dispute with the adult,
 - Be capable of giving, refusing, or revoking substitute consent, and
 - Be willing to comply with the duties.

A Health Care (Consent) and Care Facility (Admission) Act. [RSBC 1996]. Chapter 181

Provincial Health Services Authority

If no one from the above list of substitute decision makers is available or qualified or there is a dispute about who is to be chosen, the health care provider must choose a person, including a person employed in the office of the Public Guardian and Trustee, authorized by the Public Guardian and Trustee.

Health Care Plan: A health care plan is developed by a health care provider, and is signed and dated by both the health care provider and the substitute decision maker. The health care plan should contain the following information for an immunization to be given:

- Client identification (name and date of birth)
- Statement that the person providing consent has reviewed and understood the vaccine-specific Standard Information
- Name of vaccine series
- Statement of consent
- Date of consent
- Signature of health care provider and substitute decision maker

7.2 Process for Obtaining Substitute Consent

The immunization provider starts from the presumption of capability to understand the Standard Information (as defined in <u>Section 3</u> and <u>Section 4.1, Step 4</u>). However, if the adult is assessed as incapable of giving or refusing informed consent for immunization, consent can be obtained from the presenting adult's SDM. The adult's SDM may also provide consent through the use of:

- The immunization consent form, or
- The health care plan.

The following consent forms may be used for this purpose: HLTH 2387 "Consent for Influenza Vaccine for Adults Assessed as Incapable of Giving Informed Consent" and HLTH 2389 "Consent for Vaccines for Adults Assessed as Incapable of Giving Informed Consent". These forms are available on the BC Centre for Disease Control (BCCDC) website at: http://www.bccdc.ca/health-professionals/clinical-resources/immunization/informed-consent.

- a) Immunization Consent Form: When the adult's SDM provides consent by means of a signed consent form, it is valid for the period of 12 months and the immunization series can commence at any time during this period. The exception to this is when consent has been given by a TSDM. In this instance, the vaccine series must be initiated within 21 days of the date the consent form was signed. A signed consent is valid only for 21 days but if consent is for a series of vaccines (i.e., it is a plan for minor health care) the duration can be for 12 months as long as the vaccine series is initiated within 21 days of the consent being signed.
- **b)** The Health Care Plan: When a SDM provides consent by means of a health care plan, three conditions must be met:
 - 1. The immunization provider must see the health care plan to confirm that it authorizes the specific immunizations.
 - 2. The immunization provider must confirm the SDM has consented to the health care plan evidenced by the substitute decision maker's signature.
 - 3. The immunization provider must initiate the vaccine series within 12 months of the health care plan being signed.

Provincial Health Services Authority

An immunization provider is not required to do more than make the effort that is reasonable in the circumstances to obtain substitute consent. If a qualified SDM is not available or they did not provide consent in advance, the immunization provider defers the immunization and provides direction on what is required for consent.

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(Note: where indicated by section numbers definitions are taken from the <u>Health Care (Consent and Care Facility (Admission) Act (HCCCFAA)</u>)