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1.0 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 series which applies to all doses in a vaccine series.

This standard is limited to describing the process to be followed in obtaining consent for a vaccine series. 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 developed by a provincial Informed Consent Working Group and represents extensive consultation with public health nurses and nurses delivering immunization services in First Nations communities, solicitors from the Ministry of the Attorney General, 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), a program of the BC Ministry of Health.

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 College of Registered Nurses of BC (CRNBC).



2.0 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

3.0 GENERAL DEFINITIONS

Note: Refer to [Section 7.0](#) 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 his or her own behalf or for another individual. This may be a formal or informal agreement.

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

Child/Infant/Minor: anyone under the age of 19 years.

Client: the individual presenting 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 (or representative) to immunization services, after being provided with Standard Information about the vaccine(s), and demonstrating an understanding of the Standard Information and that the information applies to the individual being immunized.

Mature Minor: an individual under the age of 19 years who is capable of providing informed consent to his or her own health care.

Parent/Representative 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 a person to whom a parent/representative has given delegated authority to make decisions with respect to the immunization of a child (see 4.1f Delegated Authority).

Single dose: one dose of a vaccine in a schedule.

Standard Information addresses:

1. That consent is obtained for a vaccine series
2. That consent is valid until completion of the series or consent is revoked
3. Vaccine information contained in HealthLinkBC Files or other provincial resources as 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.

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 of 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: a vaccine given one or more times to fulfill a schedule. The schedules for each vaccine series and age of administration may vary depending upon the client-specific situation.



Examples of vaccine series are:

a) Routine Infant Series:

- Diphtheria/Pertussis/Tetanus/Hepatitis B/Polio/Haemophilus influenzae b; pneumococcal, meningococcal C vaccine per recommended provincial infant schedule.
- Measles/Mumps/Rubella (MMR) and varicella vaccine per recommended provincial infant schedule.
- Influenza vaccine: Obtain consent annually as the vaccine varies annually.

b) Routine School-Entry Series:

- Booster vaccination of Diphtheria/Pertussis/Tetanus/Polio vaccine per recommended provincial school-entry schedule.

c) Routine School-Based Series:

- Meningococcal C; hepatitis B, human papillomavirus, varicella per recommended provincial school-based schedule.
- Tetanus/Diphtheria/Pertussis per recommended provincial school-based schedule.

d) Adult(s) Series:

Examples include vaccine administration for reinforcing doses, high-risk indications, travel, and unimmunized or partially immunized adults.

Note: Obtain consent annually for influenza vaccine.

4.0 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.

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 self-consented as a mature minor.

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.

Defer the consent process if a parent discloses there are differences between parents who have equal authority to consent to their child's immunization. Do not proceed until a parent reports these differences are reconciled.

Defer and immediately consult a manager/supervisor/MHO if a parent discloses there are irreconcilable differences between parents regarding the urgent administration of post exposure immunoprophylaxis (e.g., tetanus immune globulin, hepatitis B immune globulin), or if **both** parents refuse the urgent administration of post-exposure immunoprophylaxis. The matter should be brought to the attention of the Regional Director of Child Protection as soon as possible.

c) Mature Minors

Mature minors have the authority to give, refuse, or revoke consent for their own immunization. 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.

For school-based immunization programs, efforts may be first made to obtain parental/representative consent. If a student presents without parent/representative consent, it is the immunization provider's professional responsibility to inform him or her about a mature minor's right to provide consent on their own behalf. Proceed with the consent process according to Health Authority guidelines.



d) Foster Parents

In accordance with sections 47 and 94 of the *Child, Family and Community Service Act*¹ a foster parent/caregiver has the authority to consent to immunization for a child in his or her care. It is not necessary to ask the foster parent for proof of authority.

Immunization is regarded as part of routine health care recommended by immunization providers 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*². 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 a question about who has authority to consent, contact the child's social worker for clarification.

e) Other Representative(s)

When a child is in the care of an individual other than a parent and that individual makes health care decisions for the child, he or she may consent to immunization. (e.g., grandmother/aunt who is raising the child, home stay parent of international student).

f) Delegated Authority

A parent/representative can delegate authority to or revoke authority from another person to give consent for his or her child's immunization. A note must be provided which includes the following information:

- name of parent/representative and his or her relationship to the child,
- name and birth date of child,
- name of person given authority to consent.
- date and signature of parent/representative who has delegated his or her authority

¹ *Child, Family and Community Service Act, Chapter 46* available at: http://www.qp.gov.bc.ca/statreg/stat/C/96046_01.htm Refer to Sections 47 (Effect of interim or temporary custody order) and 94 (Agreements with caregivers)

² 1.01(f) of the *Family Care Home Agreement*



Even though an adult presenting for immunization may have delegated his or her authority to consent to a representative, the immunization provider must still seek consent from the presenting adult. For example, when a developmentally delayed adult presents for immunization and is accompanied by a support worker, the immunization provider must assess the adult first to determine if he or she is capable of giving or refusing informed consent³. Refer to [Section 7.0](#).

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) Children

i) Infants/Pre-school children

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

ii) Mature minors

There is no legal age of consent for health care in BC. Children under the age of 19 years can legally consent to or refuse immunization on their own behalf if they demonstrate capability and understanding of the Standard Information.

b) Adults

Every adult is presumed capable of giving, refusing, or revoking consent for immunization unless the immunization provider assesses otherwise. “Given time and given the necessary information and support, most adults can make their own decisions.”⁴

The immunization provider should first seek consent from the adult presenting for immunization. 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 he or she consents to immunization).

³ [Health Care \(Consent\) and Care Facility \(Admission\) Act. \[RSBC 1996\]](#). Chapter 181

⁴ BC’s Adult Guardianship Law



In instances where an adult is assessed as incapable of giving or refusing informed consent refer to [Section 7.0](#)

STEP 3: PROVIDE STANDARD INFORMATION

Provide Standard Information for each vaccine series before administration of vaccine.

Standard Information addresses:

1. That consent is obtained for a vaccine series
2. That consent is valid until completion of the series or consent is revoked
3. Vaccine information contained in BCHealthLink 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

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 judgment to confirm the person providing consent understands the Standard Information.

Ways to assess understanding include:

- assessing non-verbal cues
- assessing questions
- clarifying reasons for silence or refusal to engage in discussion.

Defer the consent process and do not proceed with immunization if understanding is not demonstrated.



STEP 5: PROVIDE OPPORTUNITY FOR QUESTIONS

Ask the person providing consent if they have any questions and answer to his or her satisfaction.

STEP 6: CONFIRM CONSENT

Upon completion of steps 1 to 5, confirm the person providing consent is ready to proceed (e.g., “Are you ready to proceed?”).

STEP 7: DOCUMENT CONSENT OR REFUSAL

Document that informed consent has been given or refused according to Health Authority guidelines (e.g., iPHIS/PANORAMA, PARIS, paper record).

When mature minor consent or refusal is obtained, identify in the documentation that it was the decision of the mature minor.

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, 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
- statement of consent or refusal
- name of 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 series
- date of consent
- name 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*.

Effective Period:

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

A refusal is effective until consent is obtained. Individual circumstances to a prior refusal to vaccination may change; these include medical issues such as 'outgrowing' an egg allergy, and philosophical changes in stance, 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. These dynamic circumstances should be considered in future approaches to offer immunization services to avoid missed opportunities for vaccination.

4.2 Subsequent Visits in a Series

Confirm that documentation for consent for series is in place.

Assume that consent for 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 B.C. after January 2008. You do **not** have to contact the site where the consent for the series was obtained **or** confirm the name of the person who gave the consent for the series. Consent for series is documented in the original record and does **not** need to be repeated.

Obtain informed consent when the 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.

Discuss with the client new and significant changes to the vaccine information (e.g., changes to contraindications, precautions or adverse events.) The entire consent process does not need to be repeated.

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



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 client's methods of communication and hearing, language and cognitive abilities)].

- Provide Standard Information:**
Standard Information addresses:
 1. That consent is obtained for a vaccine series
 2. That consent is valid until completion of the series or consent is revoked
 3. Vaccine information contained in BCHealthLink 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 informed consent if he or she is ready to proceed).

- Document** consent or refusal.



6.0 CONSENT FOR SCHOOL-BASED IMMUNIZATION PROGRAMS

The consent forms for the grades 6 and 9 programs are available on the BCCDC website at: <http://www.bccdc.ca/imm-vac/VaccinesBC>.

Decisions regarding the printing, distribution, collection, and storage of these forms are to be made by local Health Authorities.

7.0 IMMUNIZATION OF ADULTS ASSESSED AS INCAPABLE OF GIVING OR REFUSING INFORMED CONSENT

If an adult is assessed as incapable of giving or refusing informed consent, obtain consent from the adult's personal guardian, if one has been appointed under the *Patients Property Act*; a representative named by an adult in a representation agreement, if the adult has one; or a temporary substitute decision maker. Consent may also be provided by a health care plan.

7.1 Definitions

Adult assessed as incapable of giving or refusing informed consent: a person who does not have the ability to understand the Standard Information and that it applies to him or her.

Substitute Decision Makers (Note: where indicated by section numbers definitions are taken from the *Health Care (Consent) and Care Facility (Admission) Act* (HCCCFAA):

(i) Personal Guardian: a committee of a person who is declared under the *Patients Property Act* to be:

- (i) incapable of managing himself or herself, or
- (ii) incapable of managing himself or herself and his or her affairs.

(ii) 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.



(iii) Temporary Substitute Decision Maker (TSDM): A person chosen by a health care provider as provided for in the HCCCFAA to make health care decisions.

s.16 (1) To obtain substitute consent to provide major or minor health care to an adult, a health care provider must choose the first, in listed order, of the following who is available and qualifies under subsection (2):

- (a) the adult's spouse;
- (b) the adult's child;
- (c) the adult's parent;
- (d) the adult's brother or sister;
- (d.1) the adult's grandparent;
- (d.2) the adult's grandchild;
- (e) anyone else related by birth or adoption to the adult;
- (f) a close friend of the adult;
- (g) a person immediately related to the adult by marriage.

(2) To qualify to give, refuse or revoke substitute consent to health care for an adult, a person must

- (a) be at least 19 years of age,
- (b) have been in contact with the adult during the preceding 12 months,
- (c) have no dispute with the adult,
- (d) be capable of giving, refusing or revoking substitute consent, and
- (e) be willing to comply with the duties in section 19.

(3) If no one listed in subsection (1) is available or qualifies under subsection (2) or if 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.

(4) A health care provider is not required to do more than make the effort that is reasonable in the circumstances to comply with this section.

Authority of a temporary substitute decision maker:

s.17 (1) Subject to section 9 (2), a person chosen under section 16 has the authority to decide whether to give or refuse substitute consent.

(2) The health care provider must, no more than 21 days before that health care begins, confirm in writing that

- (a) the adult is still incapable, and



(b) the person who earlier consented to the health care being provided confirms that the health care should begin.

(2.1) Despite subsection (2) and whether or not the health care that is the subject of the decision made under subsection (1) has begun, if at any time a health care provider has reasonable grounds to believe that the adult may be capable of giving or refusing consent to health care, the health care provider must again determine whether the adult remains incapable.

(2.2) If, at any time after a decision is made under subsection (1), the adult is capable of giving or refusing consent to health care

- (a) the authority to give or refuse substitute consent to health care for the adult is terminated,
- (b) the decision made under subsection (1) is rescinded, and
- (c) before the health care that is the subject of the decision made under subsection (1) is begun or continued, the adult must give consent to that health care.

(2.3) Subsection (2.2) does not invalidate anything that is otherwise validly done before the decision made under subsection (1) is rescinded.

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 Obtaining substitute consent

When the adult is assessed as incapable of giving or refusing informed consent for immunization, consent can be obtained from the adult's substitute decision maker (i.e., personal guardian, representative, or TSDM) or provided by a health care plan.

If the adult's substitute decision maker is not present during the immunization visit, he or she must provide consent in advance of the visit by means of a signed consent form) or a 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", HLTH 2388 "Consent for Pneumococcal 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/imm-vac/VaccinesBC>.

When consent is provided by means of a signed consent form, the immunization series can commence at any time. 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, and is valid for the remainder of the series.

When substitute consent is provided by means of a health care plan, two conditions must be met:

- (a) the immunization provider must see the health care plan to confirm that it authorizes the specific immunizations. The health care plan evidences the consent.
- (b) the immunization provider must initiate the vaccine series within 12 months of the health care plan being signed.

The provisions of the HCCCFAA authorize an immunization provider to act upon consent given on behalf of an adult living in a care facility.

The immunization provider must confirm in writing that the adult to be immunized is incapable of giving or refusing informed consent to the immunization at the time the immunization is to be given.



8.0 REFERENCES

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