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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 expedited approach.

This methodology describes a process for obtaining consent to immunization, using the standardized practice of consent for a vaccine series. This consent applies to all future immunization visits for the series.

This guideline is limited to describing the consent process for a vaccine series. An assessment of the individual's health is also an essential component of the decision to immunize, but 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 guideline 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, and operational and policy managers from the MCFD.

Public health nurses and nurses delivering immunization services in First Nations communities adopted this standard of practice for informed consent for immunization in January 2008. This 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

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

3.0 DEFINITIONS

Adult: anyone 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. This may be a formal or informal agreement.

Capability: the ability to understand the Standard Information contained in vaccine-specific BC Health Files.

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

Client: the individual presenting for immunization services.

Confidentiality: to protect personal information from disclosure to unauthorized individuals.

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

Health File: a provincial information document that outlines the Standard Information about a vaccine.

Informed consent: voluntary agreement of a capable individual (or representative) to immunization services after having been provided with Standard Information about the vaccine.

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



Parent/Representative: an individual authorized to consent to immunization on behalf of a child or another person (i.e., is authorized to make health care decisions for that child or person).

Single dose: one dose of a vaccine to fulfill a schedule.

Standard Information addresses:

1. The voluntary nature of immunization
2. That consent is obtained for a vaccine series
3. That consent is valid until completion of the series or consent is revoked
4. Vaccine information as outlined in BC Health Files:
 - **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 combination of antigens that stimulate an immune response to protect against specific disease(s).

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 are:

a) Routine Infant Series:

- Diphtheria/Pertussis/Tetanus/Polio/Haemophilus influenzae b; hepatitis 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 since protection for specific strain of influenza varies each year.

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 [BC Health File(s)]

Step 4: Confirm Understanding of Standard Information

Step 5: Provide Opportunity for Questions

Step 6: Confirm Consent

Step 7: Document Informed Consent or Refusal

Step 1: Determine Authority to Provide Informed Consent

a) Adults

Adults have the authority to give, refuse or revoke consent for their own immunization unless the health care provider assesses otherwise.

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 to a vaccine series.

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. 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 health care provider's professional responsibility to inform them 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 their 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 health care providers and is implicitly part of the plan of care developed for the child. 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.

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*



If a foster parent discloses that the child is in foster care by agreement, the parent may retain the authority to consent. In these circumstances, contact the child's social worker for advice on how to proceed unless satisfied that the social worker has authorized the foster parent to consent.

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, they may consent to immunization. (e.g., grandmother/aunt who is raising the child, home stay parent of international student).

If an adult is incapable of giving or refusing consent, obtain consent from the adult's committee or guardian, if one has been appointed; a representative appointed by the adult under a representation agreement, if the adult has one; or a temporary substitute decision maker.¹

Step 2: Assess Capability to Give Informed Consent

Assess if the person providing consent is capable of giving informed consent (i.e., assess language, hearing and cognitive abilities).

a) Children

i) Infants/Pre-school children

Infants and young children do not have decision-making capability. They require a capable person to make 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 health care provider assesses otherwise.

In instances where an adult is not capable of giving informed consent defer the immunization, and obtain informed consent from their representative.

¹ Health Care (Consent) and Care Facility (Admission) Act. [RSBC 1996]. Chapter 181. Available at: http://www.qp.gov.bc.ca/statreg/stat/H/96181_01.htm



Step 3: Provide Standard Information

a) **Provide Standard Information for each vaccine series before administration of vaccine.**

b) **Standard Information** addresses:

1. The voluntary nature of immunization
2. That consent is obtained for a vaccine series
3. That consent is valid until completion of the series or consent is revoked
4. Vaccine information as outlined in BC Health Files:
 - **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 their 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, 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, 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 of person consenting or refusing
- relationship of the person consenting to the person being immunized, if not the same

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 person being immunized, if not the same
- 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 length of series consented to, unless consent is revoked.

A refusal is effective until revoked.

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.

On subsequent visits within a vaccine series the immunization provider is ***not required*** to repeat the Standard Information unless:

- i. the person providing consent asks that information be repeated or requests further information
- ii. the series was started by a BC physician or an immunization provider outside of BC
- iii. the immunization provider is advised to do so by the BC Centre for Disease Control due to a newly recognized major adverse event or contraindication.



5.0 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., hearing, language, cognition)].

- Provide Standard Information:**
 1. Confirm the voluntary nature of immunization
 2. Advise that consent is obtained for a vaccine series and is valid until completion of the series or consent is revoked
 3. Provide the vaccine information as outlined in BC Health Files:
 - **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 person providing consent understands the Standard Information).

- 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.



6.0 REFERENCES

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