

## SECTION 2- INFORMED CONSENT

### Table of Contents

<b>1.0</b>	<b>PURPOSE AND SCOPE.....</b>	<b>1</b>
<b>2.0</b>	<b>ELEMENTS OF INFORMED CONSENT .....</b>	<b>2</b>
<b>3.0</b>	<b>DEFINITIONS.....</b>	<b>2</b>
<b>4.0</b>	<b>STEP BY STEP PROCESS FOR OBTAINING INFORMED CONSENT .....</b>	<b>5</b>
<b>4.1</b>	<b><i>INITIAL VISIT.....</i></b>	<b>5</b>
	Step 1:Determine Authority to Provide Informed Consent .....	5
	Step 2:Assess Capability to Give Informed Consent .....	7
	Step 3:Provide Standard Information .....	8
	Step 4:Confirm Understanding of Standard Information .....	8
	Step 5:Provide Opportunity for Questions.....	9
	Step 6:Confirm Consent.....	9
	Step 7:Document Consent or Refusal.....	9
<b>4.2</b>	<b><i>SUBSEQUENT VISITS IN A SERIES.....</i></b>	<b>10</b>
<b>5.0</b>	<b>CHECKLIST FOR OBTAINING INFORMED CONSENT FOR A VACCINE SERIES .....</b>	<b>11</b>
<b>6.0</b>	<b>CONSENT FOR SCHOOL-BASED IMMUNIZATION PROGRAMS .....</b>	<b>12</b>
<b>7.0</b>	<b>REFERENCES.....</b>	<b>13</b>

## 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 and or 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

**Consent to health care** under the *Care Consent Act*, applies to a person **of any age**. That means that a person of any age can consent to their own health care as long as they are capable of understanding and appreciating the consequences of that decision.(s.6 (4) CCA)

This standard is established by territorial legislation (Yukon Care and Consent Act), and is congruent with Standards for Professional Nursing Practice developed by the Yukon Registered Nurses Association (YRNA) revised in 2008.

## 2.0 ELEMENTS OF INFORMED CONSENT

- specific to immunization service
- client-centered
- voluntary
- obtained without fraud or misrepresentation
- assesses persons capability to appreciate and understand in order to provide informed 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:** any person 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 to appreciate and understand the Standard Information contained Yukon approved/endorsed vaccine information sheets.

Capability is specific to each decision.

Capability is dependent on the complexity of the decision to be made and the abilities and maturity of the individual.

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

**Client:** the individual presenting for immunization services.

**Confidentiality:** to protect personal information from disclosure except as authorized by law.

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

**Yukon Approved/Endorsed Information Sheets:** a territorial 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 and having understood Standard Information about the vaccine.

**Mature Minor:** While Yukon does not have a legislative basis for the term "Mature Minor" for the purposes of this document it will be defined as any 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). This may include the situation in which the parent has given written authority to another person to act on behalf of the parent with respect to the immunization of the child. That is, gives a note to the person that brings the child in for immunization that states they, the parent, have given permission for the other person to give consent for their child's immunizations. The health care provider must verify that the note includes the following: client identification (name and date of birth), statement that the person providing consent has reviewed and understood the Yukon Approved/Endorsed Immunization Information Sheets, statement of consent, name of vaccine or vaccine series, date of consent, name of person consenting, relationship of the person consenting to the person being immunized). This may apply to consent for series (such as with INFANRIX hexa™ at 2, 4, & 6 months) or to a single immunization. It is important to document whether consent has been given for a single immunization or for a vaccine series.

**Revoked consent:** if at any time the person who gave consent changes their mind and no longer wants to consent. In these circumstances suspend the consent and discuss this with your supervisor. Clear documentation is required to reflect the revoked or suspended consent following Community Nursing Guidelines.

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

**Standard Information addresses:**

1. The voluntary nature of immunization
2. That consent is sought for a vaccine and/ or a vaccine series
3. That consent is valid until it is revoked. (It's still "valid" after the series is completed, it's just no longer operative).
4. Vaccine information as outlined in Yukon Approved/Endorsed Immunization Information Sheets
  - **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; appropriate care**
  - **Possible serious or severe adverse events and their frequency; appropriate follow-up**
  - **Contraindications**
  - **Disease(s)** being prevented.

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**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 Territorial 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 Territorial school-entry schedule.

**c) Routine School-Based Series:**

- Meningococcal C; hepatitis B, human papillomavirus, per recommended territorial school-based schedule.
- Tetanus/Diphtheria/Pertussis per recommended territorial 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 (Yukon Approved/Endorsed Immunization Information Sheets)
- 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 determines that the adult lacks capacity to consent.

##### b) Parents

Parents have the authority to provide consent for their child **except**,

- (i) when their decision-making rights have been legally revoked or suspended (e.g. child in care, see next paragraph) **or**
- (ii) when their child has the capacity to consent as a mature minor.

In situations where the child is **not** a "mature minor" (is not capable of consenting):

As a matter of due diligence the health care provider should ask the parent or parents if the child is in care under the Child and Family Services Act , or if a court has made an order suspending or revoking either or both of their parental rights.

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

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/CMOH 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 immediate supervisor **immediately**.

**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 Yukon. Mature minor authority takes precedence over parental authority.

For school-based immunization programs efforts will be first made to obtain parental/representative consent. If a student presents with or 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 despite the consent/refusal to consent given by the parent(s). Proceed with the consent process according to Community Nursing guidelines.

If a mature minor refuses the urgent administration of post exposure immunoprophylaxis (e.g., tetanus immune globulin, hepatitis B immune globulin), the matter should be brought to the attention of the immediate supervisor **immediately**.

**d) Foster Parents**

For a child in the care of Family and Children's Services, there must be a written signed consent on the clients chart from Family and Children's Services or legal guardian in order for the health care provider to immunize. Where there is doubt of guardianship the health care provider will contact Family and Children's Services to ascertain guardianship which will determine who gives legal consent.

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.

**e) Other Representative(s):**

- (i)** 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 have the authority to consent to immunization. As a matter of due diligence, where an extended family member presents for the purpose of giving consent, the circumstances must be assessed to determine their legal authority.
- (ii)** If an adult is incapable of giving or refusing consent, obtain consent from the adult's committee or guardian or a temporary substitute decision maker. (A person who is helping an adult under a representation agreement does not have the authority to consent or refuse consent to health care on behalf of that adult.: 15(3) Decision Making, Support and Protection to Adults Act.)

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**Step 2: Assess Capability to Give Informed Consent**

All adults (19 years and older) are presumed capable of making their own health care decisions until the contrary is determined by the health care provider.

Assess if the person providing consent is capable of giving informed consent based on clinical observations including communication needs, barriers to communication and factors that may affect decisional capacity (i.e. Medication, environment, language, culture, fluctuating lucidity and peer pressure).

**a) Children**

Children are not presumed to be capable of making their own health care decisions, so a more careful assessment of capability to consent is required.

**(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 or has lost their legal right to give consent on the child's behalf.

**(ii) Mature minors**

There is no minimum legal age of consent for health care in Yukon. 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.

Obtaining Consent from a client is a process which is based on capacity not age, however, nurses recognize the varying capability of adolescents. Due to recognized varying capability of adolescents, distinctions are made according to age *groups for practical purposes only*.

**For these reasons, the following are guidelines only:**

Generally, adolescents ages 16-18 years have the same capability as adults to understand and appreciate the consequences of their health care decisions, including immunizations; adolescents' ages 14-15 years vary in capability to make decisions about immunizations; generally, adolescents ages 13 years and younger do not have the capability to make decisions about immunizations.

If the child is capable, the parent/legal guardian has no role unless the child consents to the parent/legal guardians' involvement. Furthermore, if the child is capable to consent to treatment, he or she is also entitled under ATIPP to have his or her personal information kept confidential.



**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.**

**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 or vaccine series
3. That consent is valid until completion of the series or consent is revoked
4. Vaccine information as outlined in Yukon Approved/Endorsed Immunization Information Sheets.
  - **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.

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**Defer the consent process and do not proceed with immunization** if appreciation or 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**

**For Adults:** document in iPHIS that informed consent has been given or refused according to Community Nursing guidelines, Community Health Nursing Program Manual Volume 4; iPHIS Orientation Manual.

**For Mature Minors:** document in iPHIS that informed consent **or** refusal was obtained. If consent was given by the mature minor, clearly identify this in the documentation and include a statement of the assessment of capacity, i.e.) the client is able to appreciate and understand the consequences of their decision. Document according Community Nursing guidelines See Community Health Nursing Program Manual Volume 4; iPHIS Orientation Manual.

The person providing consent may provide consent in person, in writing, or by telephone. As a matter of due diligence it is the health care provider's responsibility to ascertain the identity and legal authority of the person providing consent.

Any form of approved Community Nursing **written documentation** (e.g., consent form, handwritten note) 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 provider still has to assess whether the person consenting has authority to consent in the circumstances.

The following elements must be documented for telephone consent:

- 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 provider still has to assess whether the person consenting has authority to consent in the circumstances.
- name of person obtaining informed consent

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

A refusal to consent is effective until revoked.

#### **4.2 SUBSEQUENT VISITS IN A SERIES**

Confirm that documentation for consent for series is in place.

With the client, review steps 3 through 6 and continue iPHIS documentation as outlined in step 7.

## 5.0 CHECKLIST FOR OBTAINING INFORMED CONSENT FOR A VACCINE SERIES

- Determine authority** to provide informed consent.
  
- Assess capability** to give informed consent based on clinical observations including communication needs, barriers to communication, factors that may affect decisional capacity (e.g., medication, environment, language, culture, fluctuating lucidity, or peer pressure).
  
- 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 Yukon Approved/Endorsed Immunization Information Sheets:
    - **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 as per the above checklist**

## **6.0 CONSENT FOR SCHOOL-BASED IMMUNIZATION PROGRAMS**

Prior to school based clinics, the Community Health Centre will send out consent forms and vaccine specific information to the student's home address.

The consent forms and vaccine specific information for the grade 6 and 9 programs are available from the Community Nursing Office.

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