



Yukon Immunization Program Manual

Section 2- Informed Consent



SECTION 2 – INFORMED CONSENT

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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 document 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 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

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; [Care Consent Act](#), and is congruent with [Standards for Professional Nursing Practice](#) developed by the Yukon Registered Nurses Association (YRNA) revised in 2019.

2.0 ELEMENTS OF INFORMED CONSENT

- specific to immunization service
- client-centered
- voluntary
- obtained without fraud or misrepresentation
- assesses person's 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.

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

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 documentation standards.

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

Standard Information:

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 is 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.

Substitute Decision Maker: An individual with the authority to assist or make health care decisions on behalf of an incapable adult.

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. 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 conjugate, meningococcal conjugate, rotavirus, Measles/Mumps/Rubella (MMR) and varicella vaccine per recommended territorial infant schedule.
- Influenza vaccine

b) Routine School-Entry Series:

- Booster vaccination of Diphtheria/Pertussis/Tetanus/Polio/ Haemophilus influenzae B, Measles/Mumps/Rubella (MMR) and varicella vaccine per recommended territorial school-entry schedule.

c) Routine School-Based Series:

- Booster vaccination of Tetanus/Diphtheria/Pertussis per recommended territorial school-based schedule.
- Meningococcal quadrivalent and HPV-9 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.

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 in which case consent must be given on an adult's behalf by a substitute decision maker.

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):

- If authority to consent is in question, 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 minor 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) and to assess their capability to consent. Capability of the individual is determined throughout the appointment. Proceed with the consent process according to Yukon Immunization Program guidelines.

If at any point during an immunization appointment you feel that the individual could not be deemed capable of consenting, pause and suggest that the parent/guardian be involved in the decision.

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

A child in the care of Family and Children's Services is able to provide consent as a mature minor if deemed capable by the health care provider. If not deemed capable of consenting, 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.)

Step 2: Assess Capability to Give Informed Consent

Assess if the person providing consent is capable of giving or refusing 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) Adults

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. This includes the presumed capability of giving, refusing, or revoking consent for immunization.

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

b) 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, but adolescents do have varying levels of capability. A minor is considered capable if they demonstrate the ability to understand the standard information provided

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 Access to Information and Protection of Privacy Act (ATIPPA) to have his or her personal information kept confidential.

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.

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

a) Adults

Document in Panorama that informed consent has been given or refused according to Yukon Panorama User Manual. See Yukon Panorama User Manual Section 7.5 Record Consent and Section 7.4 Special Considerations and Deferrals.

b) Mature Minors

Document in the comments box in Panorama 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, (e.g., “The client is able to appreciate and understand the consequences of their decision”). Document according to Yukon Panorama User 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 **written documentation** (e.g., consent form, handwritten note) must be uploaded to Panorama and 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.

Length of consent

These times reflect key contact points with individuals and families. When inputting consent into Panorama, please end date the consent as outlined below:

- Birth to 4 years (consent effective to child's 4th birthday)
- 4 years 1 day to 10 years (consent effective to child's 10th birthday)
- 10 years 1 day to 13 years (consent effective to child's 13th birthday)
- 13 years 1 day to 19 years (consent effective to child's 19th birthday)
- Adult (19 years of age and older) (consent effective to end date: leave blank)

A refusal to consent is effective until revoked.

Written consent forms are only available for Yellow Fever Vaccine and School Immunization Program

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 Panorama 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 and that the information applies to the person being immunized. Assess non-verbal cues, clarify reasons for silence or refusal to engage in discussion if present and ask questions to confirm understanding).
 - 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, refusal, or deferral 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 school program consent forms and vaccine specific information for the grade 6 and 9 programs are available from the Immunization Program and online at the [Yukon Immunization](#) website.

7.0 REFERENCES

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APPENDIX A: SCRIPT FOR OBTAINING INFORMED CONSENT FROM A MINOR

Step 1: Determine Authority to Provide Informed Consent

Introduce yourself and determine if the client is interested in immunization.

1. “Hello, my name is [name]. I am a [professional designation] and I will be giving you some information about [vaccine name] and asking you some questions. Before we begin, do you have any questions? Feel free to ask me questions at any time during our conversation.”
2. “Did you discuss getting this vaccine with your parent or guardian? If yes, what did they say?” If not, encourage client to talk with a parent or guardian about their wishes and their decision.
3. “For us to get consent to give you this vaccine, I’ll need to go over a few things with you. Is that ok?”

Step 2: Assess Capability to Give Informed Consent

Communicate with the client in a way they can understand and that considers any barriers.

- Assess language, communication methods, hearing, cognitive abilities
- Use clinical judgement. If the minor does not appear to be able to provide informed consent, consider phoning the parent or guardian for verbal consent so the minor is not denied an immunization opportunity.

Step 3: Provide Standard Information

1. “I am going to review a few pieces of information about [vaccine name] so you are fully aware of what to expect. Feel free to ask any questions.”
 - Vaccine process
 - e.g., “The vaccine is injected into the muscle in your upper arm and you will need a second injection in about [length of time] to be fully protected.”
 - Note: if applicable, be sure to let the client know if there is another expected vaccine in the series and the timing of the next dose.
 - Vaccine protection against illness
 - e.g., “The vaccine is effective at preventing people from getting sick with [disease name]. It also almost completely protects you from being hospitalized or dying from the illness.”
 - Benefits on a personal and community level
 - e.g., “Vaccination is the best way to protect you and others. Getting vaccinated also lowers the risk of spreading disease. By getting the vaccine, you are helping protect everyone around you.”
 - Eligibility
 - e.g., “The vaccine is available for your age group. We recommend that you get it.”

- Common side effects
 - e.g., “You can’t get [disease name] from the vaccine but you may have a reaction. Common reactions include soreness, redness and swelling where the vaccine was given. Other reactions may include tiredness, headache, fever, chills, muscle soreness, nausea, and vomiting. These are mild and should only last a few days.”
- Risks of not getting immunized
 - e.g., “Without getting vaccinated, you will be at risk of getting sick. Even if you don’t get sick, you could spread it to others who may get very sick or die.”
- Small but important risk of anaphylaxis
 - e.g., “Very rarely, people can have a severe allergic reaction to the vaccine. This is why you will need to wait for 15 minutes after the vaccine – to make sure you don’t have any reactions. If you do, we can treat you right away. If you have a severe allergic reaction after leaving, call 9-1-1 right away.”
- Screen for contraindications
 - e.g., “Do you have any allergies?”

Step 4: Confirm Understanding of Standard Information

1. Assess non-verbal cues
2. Clarify reasons for silence or refusal to engage in discussion if present
3. Ask questions to confirm understanding if uncertain
 - a. “Before we go ahead, I need to make sure you understand what we discussed. Is that ok?” Ask questions such as:
 - What are some common side effects to the vaccine?
 - What are some benefits to the vaccine?
 - Why do we have people wait for 15 minutes after vaccination?
 - How many doses of the vaccine are required?

Step 5: Provide Opportunity for Questions

1. “Do you have any questions?”

Step 6: Confirm Consent

1. “Are you ready to get your vaccine?”

Step 7: Document Consent or Refusal

When a minor consents to immunization, document this in the comments box in Panorama when you **record consent**. Clearly identify if consent was given by the minor and include a statement of the assessment of capacity (e.g., “The client is able to appreciate and understand the consequences of their decision”).

APPENDIX B: MINOR CAPABILITY ASSESSMENT PROCESS FLOWCHART

