

Standard Operating Procedures (SOP)

Title:	Obtaining Consent for Minor's Presenting to COVID-19 Immunization Clinics
Area:	COVID 19 Immunization Clinics
Effective Date:	May 10, 2021
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Approver:	Clinical Team
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1.0 **PURPOSE:**

- To provide guidance for obtaining informed consent when a minor (client under age 18) attends a COVID-19 immunization clinic.
- To determine the ability of a minor to demonstrate they understand the nature and consequences of consenting to a COVID-19 vaccine.

2.0 **DEFINITIONS:**

Capacity: For the purpose of this SOP, the ability to understand the information that is relevant to the making of a personal decision and the ability to appreciate the reasonably foreseeable consequences of the decision.

Client: For the purpose of this SOP, a client is an individual receiving an immunization.

Immunization (or vaccination): The process by which a person becomes protected against a disease by introducing a vaccine to produce immunity.

Immunization Provider (or Immunizer): For the purpose of this SOP, a professional who is authorized under the Regulated Health Professions Act to administer a COVID-19 vaccine.

Legal Decision Maker (or Guardian): A person who has legal authority to make decisions for a minor (i.e. parent, Child & Family Services, or any other court-appointed individual).

Mature Minor: For the purpose of this SOP, a person under the age of 18 who is assessed and deemed to have the capacity to provide informed consent to receiving (or refusing) a COVID-19 vaccine.

Minor: An individual under the age of 18.

3.0 **PROCEDURE:**

- 3.1 As per subsection 57(1) of The Public Health Act (the PHA), a health care professional must obtain consent from a patient, or from a person authorized to give consent on behalf of a patient before a vaccine is administered.

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- 3.2 Consent for a minor to receive a COVID-19 vaccine must be obtained from the minor's legal decision maker or from the minor themselves if they are deemed to be a mature minor. Informed consent cannot be obtained from any other caregiver accompanying the minor to the clinic, however, if the consent form was completed and signed by the legal decision maker prior to the minor arriving at the clinic, the minor may be vaccinated.
- 3.3 If a minor attends a COVID-19 immunization clinic without their parent or legal decision maker, special consideration must be given to ensure informed consent is obtained. Professionals who are experienced in assessing client capacity should be the professionals assigned to assess if the minor has the capacity to make an informed decision and provide informed consent.

Clients 16 years to less than 18 years of age:

If a client 16 years to less than 18 years of age attends a COVID-19 immunization clinic without their parent or legal decision maker, or without a consent form signed by their parent or legal decision maker, the immunization provider can provide a COVID-19 immunization if the provider reasonably believes the minor is able to understand the nature and effects of the information and/or is able to appreciate the consequences of a decision.

If the immunization provider believes the minor is **not** able to understand the nature and effects of the information and is unable to provide informed consent, written or verbal consent must be obtained from the parent or legal decision maker. All necessary information must be communicated to the parent or legal decision maker (appropriate fact sheets and consent form). The parent or legal decision maker can complete and sign the consent form and have that presented with the client at the clinic, or the immunization provider can obtain informed verbal consent over the telephone and document that consent accordingly.

The immunizer is expected to make a reasonable attempt to contact the minor's parent or legal decision maker for consent (or refusal). If the minor indicates they do not want their parent or legal decision maker contacted and cannot provide informed consent on their own, the immunization must not be administered.

Clients under 16 years of age:

If a client under the age of 16 attends a COVID-19 immunization clinic without their parent or legal decision maker, or without a consent form signed by their parent or legal decision maker, the following steps should be taken:

- The immunization provider should first attempt to obtain written or verbal consent from a parent or legal decision maker. All necessary information must be communicated to the parent or legal decision maker (appropriate fact sheets and consent form). The parent or legal decision maker can complete and sign the consent form and have that presented with the client at the clinic, or the immunization provider can obtain informed verbal consent over the telephone and document that consent accordingly. Immunization providers are

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expected to make a reasonable attempt to contact the client's legal decision maker for consent (or refusal).

- If informed consent cannot be obtained from a parent or legal decision maker, the immunizer must assess whether the minor fully understands the nature and effects of the information provided to them regarding the vaccine and the consequences of receiving a vaccine. If these requirements are met, the mature minor has capacity to give informed consent to receive (or refuse) the vaccine without parental or legal decision maker consent.
- It should be noted there is no specified minimum age for which a minor has capacity to give consent. If a mature minor has capacity to give informed consent, regardless of their age, this is valid consent to receive a vaccine. However, the younger an individual is, the higher the standard for obtaining informed consent. More time needs to be spent with younger individuals to allow for a judgment on their capacity to provide informed consent.
- Notwithstanding the above, it is recommended that a reasonable attempt be made by the immunizer to encourage the minor to involve the parent or legal decision maker in the immunization discussions and decision process for informed consent. If the minor is deemed a mature minor and has the capacity to decide with respect to whether they can be vaccinated, the views of the mature minor's parents or legal decision maker are not relevant.
- If it is determined the minor does not have capacity to provide informed consent and attempts to obtain consent from a parent or legal decision maker have gone unanswered, the minor must not be vaccinated until a time when informed consent can be provided by the parent or legal decision maker.

3.4 Components of Informed Consent for a mature minor:

Immunization providers must be certain the minor understands the following prior to administering the vaccine (with relevant vaccine fact sheets):

- the expected benefits and risks of the immunizing agent,
- the risks of the diseases in the absence of vaccination,
- the benefits to the community of immunization programs and the risks to the community of not being immunized,
- any other information (e.g. common side effects, contraindications, route of administration) that a reasonable person in the same circumstances would require in order to make a decision about the immunization, and
- the importance of immediately consulting with the person administering the immunizing agent (or with another health professional) if a reportable adverse event occurs following immunization.

The minor must be provided with sufficient time to read the information (i.e. fact sheets) about the

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vaccine and have all questions answered. The immunizer must ask the minor if they understand all information about the vaccine.

If the immunizer is unsure whether the minor understands the information or believes the minor is not ready to make a decision, the immunization must not be administered at this time unless the immunization provider is able to receive verbal or written consent from the parent or legal decision maker.

3.5 Documentation:

If a minor is deemed a mature minor and has provided valid informed consent, the immunizer must document in the client's record that the minor is considered a mature minor and has provided informed consent to receive the vaccine.

When consent is not received, or immunization is declined, the deferral should be indicated on the consent form and documented in the client's record.

3.6 Special Considerations:

Support person: Minors may express interest in having a support person (e.g. Elder, trusted adult, escort, etc.) assist them in the process of the immunization provider assessing the client's ability to provide informed consent. Reasonable effort should be made to support this practice.

Obtaining consent from Child and Family Services: There is no expectation for clinical staff to ask a minor if they are under care of Child and Family Services. Written consent from Child and Family Services may be expressed when a minor attends an immunization clinic with a signed letter by the agency along with a completed consent form. This signed letter must be retained and attached to the consent form. If a minor attends an immunization clinic without written consent from the agency, the immunizer can still proceed with vaccination if the minor is assessed as a mature minor and has capacity to provide informed consent.

If it is determined the minor does not have capacity to provide valid informed consent and the minor discloses Child and Family Services is the legal guardian and decision maker, the immunization provider must obtain written or verbal informed consent from the agency before proceeding with the vaccination. All necessary information must be communicated to the agency (appropriate fact sheets and consent form). The agency can complete and sign the consent form, or provide a signed letter that is presented with the client at the clinic. The immunization provider can also obtain informed verbal consent over the telephone and document that consent accordingly.