COVID 19 Vaccine Implementation Task Force **Standard Operating Procedures (SOP)**	
Title:	**Informed Consent Process and Consent Documentation Requirements**
Area:	COVID 19 Immunization Clinics
Effective Date:	May 30, 2021
Revised Date:	V 3.0 Dec 9, 2021
Approver:	Operations Drafted by: V.V H./E.W.

1.0 BACKGROUND:

As per subsection 57(1) of *The Public Health Act* (the PHA), a health care professional must obtain consent from a client, or from a person authorized to give consent on behalf of a client, before a vaccine is administered. Manitoba's *Informed Consent Guidelines for Immunization* states that informed consent can be given verbally or in writing. The process for obtaining informed consent (including refusal of immunization) and vaccine administration information is required to be documented in the client record.

For consent to be considered valid, the consent must be: voluntary; obtained without fraud or misrepresentation; specific to the COVID-19 vaccine and to the specific health care professional; and informed.

Obtaining Informed Consent:

Prior to obtaining consent, the client must be informed by a health care professional verbally or in writing (with relevant vaccine fact sheets) of:

- 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 health care professional must inquire if the client has previously had a reaction that could have been related to the vaccine; and take steps to determine if there are known contra-indications to administration (e.g. allergies). The client must be provided with the opportunity to ask questions related to the vaccine or the immunization process, and receive answers from the health care professional. Once the client gives their consent, the immunization can occur.

Immunizers are protected from liability under the PHA when administering a vaccine if the client or parent/legal decision maker (guardian) has provided informed consent and the immunizer acts in good faith.

For the COVID-19 Immunization Campaign, immunization data is recorded and stored on the Public Health Information Management System (PHIMS) database.

2.0 PURPOSE:

- To ensure informed consent is obtained and documented for all clients receiving an immunization.
- To provide guidance when a health care provider is not sure if informed consent has been obtained.
- To provide guidance on what to do in situations where there is a parental dispute regarding consent to vaccinate a child.

Although different clinic models are being utilized across the province, (i.e. Traditional Mass Immunization Clinic Model, Accelerated Vaccine Program (AVP)), the components of the consent process and documentation requirements remain the same.

The Traditional Mass Immunization Clinic Model typically completes the informed consent and documentation process while the client is at the immunization station. Some clinics may have an informed consent station that the client visits prior to arriving at the immunization station where health counselling and assessment take place.

The AVP Clinic Model supports clients through the informed consent process early in the clinic flow process. This allows clinic staff in the registration area to identify clients who require counselling prior to receiving the vaccine, clients who are not suitable for the vaccine (due to health conditions, age, etc.) or clients who wish to decline the vaccine, in a more timely manner before the client reaches the Immunizer. Clients who require additional information or counselling prior to immunization are referred to the informed consent station located in the registration area.

Clinical staff at the informed consent station act as the designated medical professional for clients with additional consent requirements (who were unable to consult with their own health care provider prior to their appointment), and to assist clients who have questions and/or concerns. This process ensures clients have received adequate information and the health counselling required to obtain informed consent. The AVP Model removes the responsibility of pre-immunization counselling and associated documentation in PHIMS from the Immunizer, which allows the Immunizer to focus solely on immunizing clients. Immunizers set the pace for the entire clinic with the AVP Model, and it is essential to keep this role focused to immunizing clients for maximum clinic efficiency, to mitigate backlogs in client wait times, and to reduce the number of immunization staff required.

3.0 **DEFINITIONS:**

Informed consent: Consent is considered to be “informed” when the client understands the nature of the vaccine, its gravity, any material, special or unusual risks with respect to the vaccine, is provided with any additional information about the vaccine as requested, and agrees either verbally or in writing to proceed with receiving the immunization.

Client record: For the purpose of this SOP, client record refers to the Manitoba Health COVID-19 Vaccine Consent Form or the client record located in PHIMS.

4.0 **PROCESS:**

Consent Form:
The process of obtaining consent applies to all clients presenting to an immunization clinic. Paper consent forms are required for all clients regardless of dose within the series. Clients may arrive at the clinic with a completed consent form or are provided with a paper consent form if they have arrived without one.

Registration:
During the registration process, client identification is confirmed by reviewing one (1) piece of client identification. The client consent form is then reviewed for completion. The client is asked if they have reviewed the applicable Fact Sheets and are provided with Fact Sheets as required. Fact sheet must be available to support clients in the informed consent process.

There may be instances when it has been identified that the client requires additional information/health counselling prior to the health care provider being able to obtain informed consent. Further discussions would be warranted at either the immunization station in the Mass Immunization Clinic Model or at the informed consent station in the AVP Clinic Model in the following circumstances:

Client has answered "yes" to any questions on the consent form requiring additional counselling prior to vaccine administration:

- "Yes" to questions 8, 9, or 10 and health care provider has not completed the appropriate fields under "Immunizer Provider" on the consent form prior to attending the appointment
- "Yes" to question 11 and receiving Astra Zeneca
- History of anaphylaxis to injectable therapies
- Allergy or suspected allergy to an ingredient in the vaccine
- History of adverse reaction with previous immunization/vaccine administration
- Has any additional clinical questions about the vaccine
- Client is between 12-15 years of age and has attended the clinic without a parent or legal decision maker present (or without a consent form signed by their parent or legal decision maker) and requires assessment for mature minor informed consent

Immunization or informed Consent Station:
Health care provider reviews the consent form and assesses the client's needs. To obtain informed consent, the health care provider is required to review the expected benefits and material risks of vaccine with client. This includes:

- The nature and purpose of the immunization
- What the immunization is and how it will be done
- The expected benefits of the immunization
- The risks and possible side effects of the immunization
- The risk of not having the immunization
- Contraindications to the vaccine

The health care provider will review any additional information required as per the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers.

Situations when a health care provider is unsure if informed consent has been obtained.
If a consent form has been compromised or indicates that the informed consent process has not been completed or that consent is not voluntary, for example a client has written messaging referring to not consenting to immunization (i.e. "I am being forced to have this vaccine" or something similar), additional follow-up is required as the informed consent process may not have been observed.

In order to obtain informed consent, all options need to be discussed including the option to choose COVID-19 testing, rather than COVID-19 vaccine, if public health orders allow. Confirmation of employer policy may also be needed to clarify the client's choices and understanding of consequences.

The Immunizer needs to inform the client that staff cannot provide the vaccine without informed consent. If, after discussion, the client consents to receiving the vaccine, a new consent form must be completed. Documentation of the assessment, information provided and option chosen by the client is important.

Documenting consent:
Once consent has been obtained, the health care provider is required to document in the client record. Any warnings or applicable clinic notes should be recorded in PHIMS. If the client is identified as not appropriate to receive the vaccine, and/or the client decides not to proceed with the vaccine,

documentation regarding immunization deferral within the client record is also required.

At minimum, the following elements must be documented for consent:

- Client identification (name and date of birth)
- Recording 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 health care provider obtaining informed consent

Immunization Station/Immunization Cart:
The Immunizer/Immunization Team confirms client identity by asking client to provide two client identifiers verbally. The immunization team reviews the paper consent for completion, ensuring the consent form is signed by the health care provider in the appropriate section if client answered yes to questions 8, 9, or 10 of section B. The Immunizer confirms the client has provided informed consent and client is ready to receive their vaccination by asking the client:

"I see you have completed the consent form. You have not indicated any concerns. Are you ok if we proceed with the vaccination now?" If any additional concerns or questions remain, they are addressed by the Immunizer prior to administering vaccine.

Once the immunization has been provided, the immunization data is recorded on the client record.

Documenting vaccination:
After the immunization, the following information must be recorded:

- date of administration
- name of health care professional who administered the vaccine
- name of vaccine
- lot number
- dosage
- route of administration
- location of injection site

Situations where there is a parental dispute regarding consent to vaccinate a child.
There may be circumstances where one parent/legal decision maker consents for a child to receive the vaccine and the immunizer/RHA becomes aware that the other parent or legal decision maker objects to the child receiving the vaccine. In order to ensure that the immunizer is acting in good faith and has informed consent, when an immunizer is aware that a parent objects to the children receiving the immunization, it is recommended that a cautious approach is taken to determine if informed consent has been obtained prior to immunizing that child.

Provided the child is not considered a mature minor, arguably the immunizer could rely on one parent's consent as authority to vaccinate the child since the PHA does not expressly state that both parents are required to give consent and there is strong support found in the case law and public health officials' recommendations that receiving the vaccine is in the best interest of the child.
However, it also could be argued that the immunizer no longer responsibly believed in good faith that informed consent to immunize the child was provided once they became aware that the other parent objected to the immunization and did not make further inquiries.

Given the sensitivities surrounding the COVID-19 vaccine, and that the PHA is silent with respect to whether one parent's consent is sufficient, where the immunizer is aware that a parent objects to the vaccine, it is recommended that the immunizer take additional steps to inquire into the parental objection to ensure that they have a reasonable belief in good faith that consent was provide.

Recommendations include:

- Inquire as to whether a specific parent has decision making authority for the child. There may be circumstances where a custody arrangement or court order dictates which parent is the decision maker with respect to medical decisions about the child.
- If there is no clear decision maker, it is advisable where one parent objects to the vaccine that the consenting parent be present when the vaccine is administered to the child and the Immunizer makes a record of the parent's presence in their documentation.
- Immunizer may also elect **NOT** to immunize the child until the parents solve the matter in court or suggest that the parties attend their family physician's office to administer the vaccine (since the family physician will be more familiar and have a relationship with the family) **This may be the preferable option given the sensitivities surrounding the COVID-19 vaccine.**
- Recommend that RHA's seek their own legal advice and consult their existing policies on this issue. If no such policies exist, it is recommended that they be developed.

Where the child meets the requirements to be considered a "mature minor", they must consent to receive the vaccine and parent or legal decision maker consent is not necessary. Refer to SOP Obtaining Consent for Minor's Presenting to COVID-19 Immunization Clinics. Ultimately, the immunizer and the RHA/employer must be comfortable that they meet their obligations under the PHA.

5.0 REFERENCES:

Statutory Excerpts

The Public Health Act (C.C.S.M. c. P210)

Consent required

57(1) Before administering an immunizing agent to a patient, the health professional administering it must obtain consent from the patient or from the person authorized to consent on the patient's behalf under subsection (3) or (4).

Duty to inform patients

57(2) Before obtaining consent, the health professional administering an immunizing agent must ensure that the patient or person authorized to consent on the patient's behalf is informed, orally or in writing, of (a) the expected benefits and material risks of the immunizing agent; (b) any other information that a reasonable person in the same circumstances would require in order to make a decision about the immunization; and (c) the importance of immediately consulting with the person administering the immunizing agent, or with another health professional, if a reportable event occurs.

Adult patient not competent to consent

57(3) If an adult patient is not competent to consent to the administration of an immunizing agent, the health professional administering it must ensure that the information described in subsection (2) is given to a person authorized, in accordance with the regulations, to consent on the patient's behalf.

Previous adverse reaction after immunization

58 Before administering an immunizing agent, a health professional must (a) inquire whether the patient has previously had a reaction that could reasonably have been related to the administration of an

immunizing agent; and (b) take steps, in accordance with professional standards of practice, to determine if there are any known contra-indications to administration.

The Immunization Regulation (M.R. 36/2009)
Information to be recorded on patient's health record5 Immediately after administering an immunizing agent, the health professional administering it must record the following information on the patient's health record: (a) the date of administration;
(b) the name of the health professional who administered the immunizing agent; (c) the name of the immunizing agent, its lot number, dosage, route of administration and the location on the body where the agent was administered.

The Personal Health Information Act (C.C.S.M. c. P33.5)
Notice of collection practices
15(1) A trustee who collects personal health information directly from the individual the information is about shall, before it is collected or as soon as practicable afterwards, take reasonable steps to inform the individual (a) of the purpose for which the information is being collected; and (b) if the trustee is not a health professional, how to contact an officer or employee of the trustee who can answer the individual's questions about the collection.

Revision History:

Date	Version	Status	Author	Summary of Changes
12/03/2021	#0.01	Draft	Vanessa Van Helden	Initial draft
16/03/2021	#0.02	Draft	Melody Howrlyk	PHIMS Review
17/03/2021	#0.03	Draft	Vanessa Van Helden	Accepted Melody's changes & revised SOP based on input from PHIMS trainers (J.Sarna, Joan) and further discussion from Mar 17/21 VITF AVP Planning meeting.
18/03/2021	#0.04	Draft	Vanessa VH	Incorporated feedback from Dennis Tabbernor. Added info on adding new patient into PHIMS at registration, and Observer role answering questions after immunization.
21/03/2021	#0.05	Draft	Erin/Cathy and Lori Ann – Clinical Team	
30/05/2021		Draft	Erin/Christy/Cathy	Condensed to cover Informed Consent Only. Removed clinic flow details and placed into additional clinic flow document.
Oct 5, 2021	2.0	Final	Erin	Adapted to cover informed consent and documentation requirements within all clinic models. Added additional requirements when consent form indicates that informed consent may not have taken place.
Dec 9, 2021	3.0	Final	Erin	Additional information on managing situations *where there is a parental dispute regarding consent to vaccinate a child.*