PCH Process for Obtaining Informed Consent for the COVID-19 Vaccine

1) Send/give the residents and substitute decision makers the current version of the applicable COVID-19 vaccine factsheets:
    a. COVID-19 mRNA Vaccine (Pfizer-BioNTech and Moderna)- Public Health Factsheet
    b. COVID-19 Reaction Factsheet

2) Obtain a blank copy of the current version of the Manitoba ***COVID-19 Vaccine Consent Form***: https://www.gov.mb.ca/covid19/vaccine/resources.html#forms

3) Complete the top section of the Manitoba COVID-19 Vaccine Consent Form:
    a. Sections A, B, C, D, and E completed by: check ☑ "Other" and fill in the name of the person discussing consent with the resident or substitute decision maker

4) Section A. Client Information

a. Fill in the resident's demographic information or a chart label can be affixed in this section as long as it includes the following information. If handwriting, please ensure this information is legible.
    i. Resident surname and given names
    ii. Date of birth (yyyy/mm/dd)
    iii. Sex
    iv. Manitoba Health Number (6 digits)
    v. Personal Health Information Number (9 digits)

5) Section B. Health History of Client

a. Review the resident's health record and the current medication administration record (MAR) for the questions below before discussing consent with the resident or substitute decision maker.

b. Question 1 – Do you have a fever or other symptoms that could be due to COVID-19?
    i. Indicate a response to this question at the time of consent. Check ☑ yes or no. The consent process can proceed even if the answer is "yes".
    ii. Residents who have a fever or other symptoms that could be due to COVID-19 on the day of vaccination won't be vaccinated at that time, but will have an opportunity to be vaccinated at a later date.

c. Question 2 - Do you have any known or suspected allergies (examples: food, medications, environmental)?
    i. Identify if the resident has any known or suspected allergies. Check ☑ yes or no.
    ii. For all residents, make a copy of the LTC Allergy and Intolerance Record or similar single source of truth for allergies and intolerances and attach to the consent form for the immunizer

d. Question 3 - Do you have a known or suspected allergy to polyethylene glycol (PEG), polysorbate 80 or tromethamine?
    i. Identify if the resident has any known or suspected allergy to polyethylene glycol (PEG), polysorbate 80 or tromethamine. Check ☑ yes or no.

ii. If yes, refer to the physician or nurse practitioner to assess

e. Question 4 - Have you ever had a serious reaction or condition following any vaccine?

i. Look for documentation on the LTC Allergy and Intolerance Record or similar single source of truth for allergies and intolerances.
ii. This question should also be confirmed with the resident or substitute decision maker during the live discussion.
iii. If yes, refer to the physician or nurse practitioner to assess the risk of reaction.
iv. Physicians/nurse practitioners: refer to the up-to-date information in the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers on "*People who Require Further Consultation before Immunization*"

f. Question 5 - Do you have any medical conditions that require regular visits to a doctor?

i. Check ☑ yes as residents receive routine medical care from the PCH physician or nurse practitioner

g. Question 6 - Have you received a vaccine in the last 14 days?

i. Look in the prescriber's order sheets and on the MAR for documentation of any vaccinations in the 14 days prior to the scheduled vaccination clinic (e.g. Influenza, Pneumococcal, tetanus, shingles, etc…).
ii. For new admissions in the 14 days prior to the scheduled vaccination clinic, also review the transfer information from the sending facility and their immunization record from PHIMS or eChart
iii. If the resident has received another vaccination 14 days prior to the scheduled vaccination clinic, check ☑ yes. It is recommended to list the other vaccine(s) next to this question for the immunizer.
iv. For the current guidance regarding the COVID-19 vaccine and other vaccines, refer to the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers "Clinical Practice Questions and Answers, Question 27"

h. Question 7 - Are you taking any medications that affects blood clotting?

i. Review the MAR for the following medications:

Apixiban	Dipyridamole	Ticagrelor
ASA	Edoxaban	Tinzaparin
Clopidogrel	Heparin	Warfarin
Dabigatran	Prasugrel	
Dalteparin	Rivaroxaban	

ii. If the resident is on one or more of these medications, check ☑ yes and list them on the line below question 7.

i. Question 8 - Are you pregnant, planning to become pregnant or breastfeeding?

i. Check ☑ no unless the resident is female and of child-bearing age
ii. If the resident is female and of child-bearing age, refer to the physician or nurse practitioner.
iii. If yes,

- Give the resident or substitute decision maker the additional fact sheet: COVID-19 Vaccine: Information for Pregnant and Breastfeeding Individuals
- The Health care provider or immunizer should review the expected benefits and risks of vaccination with the resident as outlined in the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers "*Vaccination Risks and Benefits for Pregnancy &/or Breastfeeding Clients/Patients*".

j. Question 9 – Is your immune system suppressed due to disease (e.g., leukemia) or treatment (e.g,. high-dose steroids)?

i. Identify residents with a suppressed immune system due to disease or treatment (see examples in table below). For full details, refer to the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers "*People who require further consultation before immunization*"

Examples (this list is not exhaustive, if unsure, consult physician or nurse practitioner):

Immunosuppressive Disease
• Active treatment for solid tumor or hematologic malignancies • Receipt of solid organ transplant and taking immunosuppressive therapy • Receipt of CAR-T therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy) • Moderate to severe primary immunodeficiency • Stage 3 or advanced untreated human immunodeficiency (HIV) infection and those with acquired immunodeficiency syndrome
Immunosuppressant Therapy

• Cancer chemotherapeutic agents (radiation, chemotherapy, immunotherapy or targeted therapies)
  ○ e.g. imatinib, nilotinib, ibrutinib
• Alkylating agents (e.g. cyclophosphamide, busulfan)
• Antimetabolites (e.g. hydroxyurea, methotrexate)
• Anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22)
  ○ Rituximab
  ○ Ocrelizumab
• High-dose systemic corticosteroids (defined as the equivalent to greater than or equal to 20 mg of prednisone for 4 or more weeks)
• Tumor-necrosis factor (TNF) blockers
  ○ Adalimumab
  ○ Certolizumab pegol
  ○ Etanercept
  ○ Golimumab
  ○ Infliximab
• Jak inhibitors
  ○ Tofacitinib
  ○ Baricitinib
• Immunosuppressants
  ○ Mycophenolate
  ○ Tacrolimus[1]

○ Azathioprine • Disease-modifying antirheumatic drugs (DMARDs) ○ Leflunomide • Immunomodulating ○ Fingolimod

[1]Not including topical tacrolimus (Protopic®)

ii. If the resident has one or more of these conditions or is on one or more of these medications, check ☑ yes

iii. If yes,

- Give the resident or substitute decision maker the additional fact sheet: COVID-19 Vaccine: Information for Individuals who are Immunosuppressed and/or have an Autoimmune Condition
- The physician or nurse practitioner should be involved in these discussions either directly or via the nurse
  - Health care provider or immunizer must review the expected benefits and risks of vaccination as per the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers *"Vaccination Risks and Benefits for Clients/Patients who are Immunosuppressed &/or have an Autoimmune Condition*"
- After the discussion, the health care provider should document their name and signature in the bottom section of the consent form under "***Clients who answer yes to questions 9, 10 and/or are receiving dose 3 (as per question 12) of section B***"

k. Question 10 - Do you have an autoimmune condition (e.g., Rheumatoid Arthritis, Multiple Sclerosis)?

i. Identify residents with an autoimmune disorder (see examples in table below). For full details, refer to the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers "*People who require further consultation before immunizatio*n"

Examples (this list is not exhaustive, if unsure, consult physician or nurse practitioner):

Autoimmune Disorder	
• Rheumatoid arthritis • Multiple sclerosis • Inflammatory bowel disease (e.g. Crohn's disease, ulcerative colitis) • Systemic lupus erythematosus • Psoriasis/Psoriatic arthritis • Polymyalgia rheumatica • Sarcoidosis • Ankylosing spondylitis • Fibromyalgia • Vasculitis • Temporal arteritis	• Addison's disease • Grave's disease • Myasthenia gravis • Mixed connective tissue disease (MCTD) • Hashimoto's thyroiditis • Granulomatosis with polyangiitis (Wegener's) • Immune thrombocytopenic purpura • Guillain-Barre syndrome • Glomerulonephritis

ii. If the resident has one or more of these conditions, check ☑ yes
iii. If yes,
- Give the resident or substitute decision maker the additional fact sheet: COVID-19 Vaccine: Information for Individuals who are Immunosuppressed and/or have an Autoimmune Condition
- The physician or nurse practitioner should be involved in these discussions either directly or via the nurse
- Health care provider or immunizer must review the expected benefits and risks of vaccination as per the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers *"Vaccination Risks and Benefits for Clients/Patients who are Immunosuppressed &/or have an Autoimmune Condition*"
- After the discussion, the health care provider should document their name and signature in the bottom section of the consent form under "***Clients who answer yes to questions 9, 10 and/or are receiving dose 3 (as per question 12) of section B***"

l. Question 11 - Do you have a history of venous sinus thrombosis in the brain or a history of heparin-induced thrombocytopenia (HIT)?

i. If the resident has a history of one or more of these conditions, check ☑ yes
ii. If yes,
- This question is relevant for people receiving the viral vector vaccines (e.g. AstraZeneca/COVISHIELD vaccine, Janssen vaccine) which we aren't currently administering in LTC

m. Question 12 – Have you received any doses of a COVID-19 vaccine?

i. Ensure that verification of vaccination status has occurred from 1 of the following sources to confirm the date and brand of previous vaccinations:
- Consent form with first and second vaccination documented
- Immunization history printed from eChart OR
- Immunization record from WRHA Public Health (i.e. Public Health Information Management System PHIMS) OR
- Copy of their Shared Health Immunization Record
- Copy of their Pan-Canadian Proof of Vaccination Credential (PVC)

ii. If the resident has had any previous COVID-19 vaccinations, check ☑ yes
iii. If yes, indicate how many vaccinations in the space provided. It is recommended to document the date of the last vaccination for the immunizer.
- Is the vaccination a first or second booster for the resident?
  - Review the risks and benefits of booster doses with resident and substitute decision maker included in the COVID-19 mRNA Vaccine (Pfizer-BioNTech and Moderna)- Public Health Factsheet
  - After the discussion, the health care provider should document their name and signature in the bottom section of the consent form under "***Clients who answer yes to questions 9, 10 and/or are receiving dose 3 (as per question 12) of section B***"

n. Question 13 – Have you had a confirmed COVID-19 infection?

i. If the resident has had a confirmed COVID-19 infection, check ☑ yes.
ii. If yes, indicate the date of symptom onset or the positive test result whichever is earlier
- Per the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers, *NACI has suggested a 3-month interval between infection and COVID-19 booster dose or 6 months from the most recent vaccine dose, whichever is longer. Given high rates of Omicron infection in community and institutional settings between December 2021 and February 2022, a proportion of the population may have boosted their immune response following exposure to the Omicron variant.*

o. Question 14 - Have you received a monoclonal antibody treatment (e.g., Sotrovimab, Casirivimab, Imdevimab) for a COVID-19 infection in the last 90 days?

i. Check if the resident has received a monoclonal antibody treatment through review of the resident's PCH health record. If the resident was admitted in last 90 days, also review the admission information, and discuss with the substitute decision maker.
ii. If the resident has received a monoclonal antibody treatment in the last 90 days, check ☑ yes.
iii. Per the Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers,
- *Manitoba public health officials recommend that COVID-19 vaccination be deferred for 90 days after receiving a passive antibody product (anti-SARS-CoV-2 monoclonal antibody) to avoid potential interference of the product with vaccine-induced immune response*
- *Administration of these products close together may result in decreased effectiveness of a COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies because the monoclonal antibodies have high affinity for the spike protein expressed by the vaccines, which could prevent the production of antibodies stimulated by the vaccine.*
- *However, if passive antibody products and a COVID-19 vaccine dose are administered within 90 days, the vaccine does not need to be repeated*
- *There is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.*
- *Vaccines other than COVID-19 vaccines, including inactivated and live vaccines, may be administered without regard to timing of anti-SARS-CoV-2 monoclonal antibodies.*

6) Section C Racial, Ethnic or Indigenous Identity

a. Ask the resident or substitute decision maker which best describes the racial or ethnic community for the resident and check the applicable box
i. African
ii. Black
iii. Chinese
iv. Filipino
v. Latin American
vi. North American Indigenous – that is, First Nations, Metis or Inuit

vii. South Asian
viii. Southeast Asian
ix. White
x. Other (specify in space provided)
xi. Prefer not to answer

b. If the resident identified as North American Indigenous, check the applicable box for which group they identify as:
   i. First Nations
   ii. Metis
   iii. Inuit
   iv. Not Applicable

7) <u>Section D. Informed Consent</u>

a. Determine if the resident has *decision-making capacity* to consent to receiving the COVID-19 vaccine.
   i. Refer to the WRHA Policy #110.000.005 Informed Consent (for Procedures, Treatments and Investigations) for the definition of *decision-making capacity*, *substitute decision maker, and witness*
   ii. If the resident cannot consent, determine the resident's *substitute decision maker*
   iii. If the substitute decision maker is Public Guardian and Trustee of Manitoba (PGT):
      - Fax the partially completed consent form (Sections A, B & C) to the PCH's or resident's Adult Services Administrator (ASA) at Public Guardian and Trustee of Manitoba. On the fax cover sheet, indicate a contact person and phone number for questions about the consent
      - The signed consent form will be faxed back to the PCH from the Public Guardian and Trustee of Manitoba (PGT)
   iv. Consider if a trained/qualified Interpreter is required when the resident or substitute decision maker has limited English proficiency

b. Meet with the resident or contact the substitute decision maker. **There must be a live discussion which can be in-person or by telephone**:
   i. Ensure the resident or substitute decision maker has received and reviewed the most up-to-date factsheets as outlined in #1
   ii. Review the answers to questions in section B as determined by the review of the resident's health record. Update any responses as required based on information from the resident or substitute decision maker
   iii. Review section C
   iv. Review the benefits and risks of the COVID-19 vaccine
   v. Provide information about vaccine side effects
   vi. Address questions or concerns. If not able to respond to the question or concern at the time, see e. below

c. Ask if the resident or substitute decision maker has read/heard and understood the fact sheet(s) regarding the vaccine(s) and is consenting to administration of the vaccine. Confirm that they have had the opportunity to ask questions about the vaccine(s) which were answered to their satisfaction.

The consent applies to all doses of the vaccine necessary to complete the primary series up to one year. The resident or substitute decision maker can withdraw consent at any time.

i. Consent by legal decision maker

- In person:
  - Following a live discussion, the substitute decision maker completes the following information under Section D Part 1 on the Manitoba COVID-19 Vaccine Consent Form:
    i. Name
    ii. Relationship (to the resident)
    iii. Phone number
    iv. Date
    v. Signature
  - A witness, other than the person obtaining the informed consent, should observe the substitute decision maker physically signing the consent form
  - The witness should sign the consent form to the right of the substitute decision maker's signature clearly printing their name with their signature

- Fax:
  - Following live discussion, the substitute decision maker can provide consent by faxing a copy of the completed consent form
  - The substitute decision maker completes the following information under Section D Part 1 on the Manitoba COVID-19 Vaccine Consent Form:
    i. Name
    ii. Relationship (to the resident)
    iii. Phone number
    iv. Date
    v. Signature

- Verbal:
  - Following live discussion by phone, the person receiving the verbal consent from the substitute decision maker completes the following information under Section D Part 1 on the Manitoba COVID-19 Vaccine Consent Form:
    i. Name of substitute decision maker
    ii. Relationship to resident
    iii. Phone number of substitute maker
    iv. Date
    v. Signature of person receiving the verbal consent
  - The substitute decision maker should repeat their verbal consent to a witness, other than the person obtaining the verbal consent.
  - The witness should sign the consent form to the right of the signature of person completing the consent form on behalf of the substitute decision maker, clearly printing their name with their signature

- **Email consent from the substitute decision maker is <u>not acceptable.</u>** Emailing of a completed consent form is not recommended due to the security of personal health information.

ii. Consent by client

- Determine if the resident can physically sign Section D on the Manitoba COVID-19 Vaccine Consent Form. As per the WRHA Policy #110.000.005 Informed Consent, the signature can be in any form or style including an "X".
  - <u>Written</u>:
    - The resident dates and signs under Section D Part 2 on the Manitoba COVID-19 Vaccine Consent Form.
    - A witness, other than the person obtaining the informed consent, should observe the resident physically signing the consent form
    - The witness should sign the consent form under the resident's signature clearly printing their name with their signature
  - <u>Verbal</u>:
    - If the resident is unable to sign the consent form, the resident can provide verbal consent.
    - A witness, other than the person obtaining the informed consent, should witness BOTH the informed consent discussion and verbal consent
    - The person receiving the verbal consent from the resident completes the following information under Section D Part 2 on the Manitoba COVID-19 Vaccine Consent Form:
      i. Date
      ii. Resident name
      iii. Signature of person receiving the verbal consent
    - The witness should sign the consent form below the signature of person completing the consent form on behalf of the resident, clearly printing their name with their signature

d. If informed consent cannot be given for the resident due to:

i. Outstanding questions or concerns:

- Seek answers to the questions/concerns and respond to the resident or substitute decision maker.
- If unable to find answers, document the discussion in the integrated progress notes of the resident's health record and refer to another healthcare professional (e.g. nurse, nurse manager, director of care, physician, or nurse practitioner) for further discussion with the resident or substitute decision maker.

ii. If the resident or substitute decision maker declines to consent:

- Document the discussion in the integrated progress notes of the resident's health record and refer to another healthcare professional (e.g. nurse, nurse manager, director of care, physician, or nurse practitioner) for further discussion with the resident or substitute decision maker.
- If informed consent is not able to be obtained after further discussion, complete the *WRHA Refusal of Treatment form (#W-00244)* with the resident or substitute decision maker and file in the resident's health record.

8) Section E. Consent for Use and Disclosure of Contact Information

a. Generally, this section does not need to be completed for PCH residents, but may be considered for residents/clients that may be returning to the community (e.g. transitional care)

9) Immunization Provider Section

a. **Clinic Location**: indicate the name of the PCH/LTC site where the vaccine clinic is being held
b. **Reason for immunization**: check ☑ Personal care home resident
c. Check off the 5 interventions performed and documented as part of the consent process
d. **Health Care Provider**: for residents with "yes" answers to questions 9, 10 and/or receiving dose 3 per question 12, the health care provider completes the printed name, signature and date
e. After vaccination, the immunizer completes the table including documentation of:
    i. Vaccine name
    ii. Date (Y/M/D)
    iii. Lot # (e.g. 2 letters and 4 numbers EW0199)
    iv. Manufacturer
    v. Route
    vi. Dose
    vii. Site
    viii. Immunizer's signature