INFORMATION & CONSENT FORM

RESEARCH TITLE: Immunogenicity and adverse events following immunization with alternate schedules of authorized COVID-19 vaccines in Canada: **MOSAIC** study (**M**ix and match of the second c**O**vid-19 vaccine dose for **SA**fety and **I**mmunogeni**C**ity)

SHORT TITLE: MOSAIC Canada study

PROTOCOL NUMBER: CT24

RESEARCHERS:

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FUNDER: COVID Immunity Task Force (CITF)

SPONSOR: Canadian Immunization Research Network (CIRN)
Dalhousie University

Introduction

You are being invited to take part in the research study named above. Before you decide, please read this form carefully so you know why the study is being done and what it involves.

Your participation in this study is completely voluntary (your choice). Take as long as you need to make your decision. You also can choose to take part in the study now, and then change your mind later at any time. Your choice will not change the quality of care that you will receive outside of this study.

We encourage you to have conversations with your family, doctors, and study team about taking part in this study and whether it is right for you. The study team will work with you to answer any

questions that you may have about the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

If you choose to participate in this study, you will be asked to sign this consent form prior to the study to let the study team know your decision. You will receive a signed and dated copy of this consent form for your records. Please keep this consent for your reference.

Why are the researchers doing the study?

Coronaviruses are a large family of viruses found mostly in animals. In humans, they can cause diseases ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). A new coronavirus was identified in an outbreak that began in Wuhan, China, in December 2019. The virus has been named SARS-CoV-2, and the infectious disease caused by the virus has been named COVID-19. The World Health Organization declared this virus as the cause of a pandemic in March 2020.

The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, sore throat or diarrhea. These symptoms are usually mild, and most people recover from the disease without needing special treatment. However, people over age 60, or those with weakened immune systems, or underlying medical problems have a higher risk of developing serious complications or dying from COVID-19. Researchers around the world are studying the virus and its effects, and working on ways to fight it, including vaccines.

Vaccines are one way to protect against disease. Vaccines work by preparing the immune system, the system in your body that fights disease, to react quickly against germs, such as viruses or bacteria, should they ever enter the body in the future. Vaccines trigger the body's defenses to produce disease-fighting antibodies. If a germ enters the body, the immune system will be prepared for it. The immune system will be able to destroy the germ before it can do harm.

The first COVID-19 vaccination programs started in Canada in December 2020. Canada has advanced purchase agreements for seven potential vaccines. Currently two mRNA vaccines (Pfizer-BioNTech and Moderna) and two vector-based vaccine (AstraZeneca and Janssen) have received regulatory approval. The mRNA and the Astra-Zeneca vaccines are being used in public health mass vaccination programs in Canada. The Janssen vaccine has not yet been used in public health programs in Canada.

A mRNA vaccine teaches our cells how to make a protein that will trigger an immune response. It does not use the live virus that causes COVID-19. When our body see the protein it then makes antibodies. These antibodies help us fight the infection if the real virus does enter our body in the future.

'RNA' stands for ribonucleic acid, which is a molecule our cells use to provide instructions for making proteins. Messenger RNA (mRNA) vaccines contain the genetic instructions for making the SARS-CoV-2 spike protein, which is found on the surface of the virus that causes COVID-19.

When a person is given the vaccine, their cells will read the genetic instructions like a recipe and produce the spike protein. After the protein piece is made, the cell breaks down the instructions and gets rid of them. The cell then displays the protein piece on its surface. Our immune system recognizes that the protein doesn't belong there and begins building an immune response and making antibodies.

A vector-based vaccine uses a virus, such as an adenovirus, as a delivery system. This "vector" virus is not the virus that causes COVID-19. Adenoviruses are among the viruses that can cause the common cold. When a person is given the vaccine, the vector virus contained within the vaccine helps our cells produce the SARS-CoV-2 spike protein. This protein is found on the surface of the virus that causes COVID-19. Our immune system recognizes that the protein doesn't belong there and begins building an immune response and making antibodies.

The AstraZeneca vaccine has been used in public health immunization programs in Canada, but some provinces are not continuing to use this vaccine. A second adenovirus virus vectored-based vaccine (Janssen Inc.) is approved but has not yet been used in public health programs in Canada.

It has been difficult for companies to make enough vaccines for all the people who need them in the world. The interruptions to vaccine supply in the face of large outbreaks has led some provinces to use a strategy to deliver as many first vaccines doses as possible. Other provinces or territories initially held back the second dose in order to deliver it according to schedule to recipients of the first dose.

However, the National Advisory Committee on Immunization (NACI) recommended that the second dose could be given up to four months after the first dose. This 0, 16-week vaccine schedule is now planned in most of Canada. However, there is not very much evidence about how well the schedule with a 4-month delay works. Secondly, when there is a vaccine shortage public health may decide to use a different brand of vaccine for the second dose. Questions of vaccine interchangeability (using different vaccines for dose one and dose 2) and delays to dose 2 of the vaccines are common issues in public health vaccine programs.

The purpose of this study is to compare the effectiveness, safety and acceptability of different dosing schedules of the COVID-19 vaccines that are available or become available in Canada, and of giving the second dose of two dose COVID-19 vaccine schedules with a different COVID-19 vaccine.

The currently available mRNA vaccines (Pfizer-BioNTech and Moderna) are two dose vaccines which were studied in schedules of either 0 and 21 days or 0 and 28 days. We will compare the

interval 0, 28 days to a 0, 112 days (16 weeks) schedule. The currently available adenovirus-vectored vaccine (AstraZeneca) is a two-dose vaccine, with the second dose given between 4 and 12 weeks after the first dose.

As new vaccines are authorized and available in Canada additional study groups may be added.

This study will look at:
1. What is the effect of different dosing intervals of the vaccines on effectiveness and safety?
2. If two doses of different COVID-19 vaccine products are used, what is the immune response?
3. What is the length of immune responses?

How will the researchers do the study?

About 1200 participants will take part in this study at 6 sites in Canada. Approximately 225 will take part at the Canadian Center for Vaccinology located at the IWK Health Centre in Halifax.

The study is looking at different vaccine combinations given at two different dose schedules (Day 0 & 28) & (Day 0 & 112). All the vaccines used in this study are authorized for use in public health programs in Canada during the COVID-19 pandemic.

This is a participant-blinded study. You will not be able to choose which vaccine you receive. You will only be told after the study is finished or in case of an emergency. This way, the results from the different groups will be handled in the same way. You will be informed whether you are receiving the second dose at Day 28 (+ 28 days) or Day 112 (- 42 to +14 days). There is a window for each visit to allow for flexibility in scheduling.

There will be different study participant visits depending on whether or not you have already received your first dose from Public Health or not. If you have received the vaccine from Public Health, we will need to obtain a copy of your vaccine record. If you received your first COVID-19 vaccine from Public Health we will collect information about that dose, and you will get your second dose in the study.

This is a randomized study. Randomized means that your vaccine group will be chosen at random (like rolling a dice). You have an equal chance of being placed in each group.

There are 12 study groups (see Table). If you have not yet had any COVID-19 vaccines ("Vaccine-naïve") you will get *both dose*s in the study. You will be randomized to one of Groups 1 through 8.

If you have had your first dose of a COVID-19 vaccine ("Vaccine-exposed") you will be randomized to receive your *second dose* in one of Groups 1 through 12. Eligibility for the study groups in people who have had their first dose depends on what vaccine they received.

Study Groups

Group	Vaccines	Dose 2
1	Moderna mRNA and Moderna mRNA	Day 28
2	Moderna mRNA and Moderna mRNA	Day 112
3	Moderna mRNA and Pfizer/BioNTech mRNA	Day 28
4	Moderna mRNA and Pfizer/BioNTech mRNA	Day 112
5	Pfizer/BioNTech mRNA and Pfizer/BioNTech mRNA	Day 28
6	Pfizer/BioNTech mRNA and Pfizer/BioNTech mRNA	Day 112
7	Pfizer/BioNTech mRNA and Moderna mRNA	Day 28
8	Pfizer/BioNTech mRNA and Moderna mRNA	Day 112
9	AZ and Moderna mRNA	Day 28
10	AZ and Moderna mRNA	Day 112
11	AZ and Pfizer/BioNTech	Day 28
12	AZ and Pfizer/BioNTech	Day 112

You can take part in this study if:
1. You are between 18 years of age and older
2. You are available for all the study visits.
3. You are in good health with stable health conditions.
4. You are not pregnant.
5. You have a record of the first dose of the authorized COVID-19 vaccine you received and have not received the second dose yet. **Or** you have not received a COVID-19 vaccine.

There are other study criteria that will be reviewed at the first visit to determine if you are eligible or not.

What will I be asked to do?

You will have 5 clinic visits and 1-2 telephone/email contacts if you are a ***vaccine naïve*** participant (have not received a COVID-19 vaccine) during a 12-month period. The total time commitment is approximately 3-4 hours.

You will have 4 clinic visits and 1-2 telephone/email contact if you are a ***vaccine exposed*** participant (received your first COVID-19 vaccine from Public Health) during a 11-month period. The total time commitment is approximately 2-3 hours.

The following procedures will be done at the study visits and contacts:

Consent - Before any study activities are performed, you will be asked to review and sign this information and consent form. This will indicate that you understand your involvement and the risks of participating in the study, and that you agree to take part in and comply with all study activities. You will receive a copy of it to keep. We will verbally reconfirm that you want to continue participating in the study at each follow-up contact.

Medical History - At the first study visit, you will be asked about your medical history; such as previous allergies, illnesses and any medications you are currently taking to ensure that you are eligible to participate in the study. If you are a female, you will be asked about your method of birth control. At follow-up contacts/visits we will ask about any changes in your health.

The informed consent can be obtained electronically and the medical history including current medications can be collected and reviewed over the phone at the screening contact. Once eligibility is confirmed you will be randomized and scheduled for your vaccine visit. Or all these activities can occur at Visit 1.

Vital Signs - Prior to each vaccination we will measure your vital signs (temperature, pulse, blood pressure and respiratory rate). At Visit #1 we also measure your height and weight to calculate your body mass index (BMI).

Demographic Information - At the first study visit we will collect your age, gender/sex and ethnicity/race.

Blood Samples - You will be asked to provide a blood sample (approximately 23 mL or 4 teaspoons/sample) at the study visits to measure your antibody testing (protection level) to the vaccine.

Some blood will be tested using different methods to measure your immune response (the level of special proteins in your blood (antibodies) that are created by your immune system) against the novel coronavirus (SARS-CoV-2). Participants in the Vaccine Naïve groups at three study centers, including Halifax, will have blood samples (approximately 40 mL or 8 teaspoons/sample) collected in addition to antibody testing.

Pregnancy Test/Birth Control - If you are a woman who can get pregnant, you will have a urine pregnancy test before the vaccination. We will ask you about your method of birth control. You must use an effective method of birth control or practice abstinence from at least 30 days prior to the study vaccination and 3 months after the last vaccination. If you become pregnant during the study, you must tell the study doctor or study nurse as soon as possible. The study doctor will keep in touch with you until the end of your pregnancy to check on your health and that of your baby.

Vaccinations - If you have not received a previous COVID-19 vaccine the first dose will be given at Visit 1 (Day 0) and the second dose will be given at Visit 2 (Day 28 + 28 days) or Visit 3 (Day 112 - 42 to + 14 days) depending which study group you are randomized to.

If you have already received one dose of a COVID-19 vaccine from Public Health, the second dose will be given at Visit 1 or Visit 2 depending on which group you are randomized to. The vaccine will be given in the upper arm (deltoid) muscle. After the vaccination, you will be asked to stay at the clinic for at least 15 minutes to monitor for any rare allergic reaction.

Contact Information - We will ask you to provide current contact information, including a phone number and an alternate contact. During the study, we will make a follow-up phone calls, emails or text messages (your preference) 7 days after you receive your vaccine(s) to remind you to complete the diary card and the acceptability survey.

We may also try to contact you to confirm follow-up visits or if you do not show up at a scheduled visit. At each visit we will confirm that your contact information remains current. We will verify again at the last visit so we can contact you in case we receive information important for your health, after you have completed the study.

Recording in the Diary - You will record information after receiving each vaccination about your symptoms in a diary for the first 7 days, if you have any.

The study nurse will provide you with a diary, a ruler and a thermometer, and instructions about how to use them. You will be asked to take your temperature and measure any redness or swelling daily for 7 days. You will also be asked to record severe reactions and any changes in your health that you experience, associated medications or doctor visits. You will return the diary card and it will be reviewed and collected at the next visit.

During the study, you should contact the study staff immediately should you have any signs or symptoms that you see as serious, if you develop any COVID-19 symptoms, if you are hospitalized or suffer any other serious or life-threatening illness. The study doctor and the study nurses will be available for the entire study period.

Acceptability Questionnaire - You will be asked to complete a paper questionnaire twice over the study. The questionnaire is looking at your opinion about the vaccines.

COVID-19 Symptoms - If you develop symptoms suggestive of COVID-19 (fever, new or worsening cough, sore throat, runny nose and/or headache) we will follow public health guidelines at that time. You may be asked to go to a testing site for collection of a respiratory sample (nasal or throat swab) to check for presence of SARS-CoV-2. Further management will be as per local public health and clinical guidelines at the time of the event. With your permission we will collect information about the test and any medical records about this illness

Prior to any study visit we will ask questions to see if you have any symptoms suggestive of COVID-19. We will provide instructions prior to the study visit on how to access CCfV to attend the study visits and whether or not you will be required to wear any personal protective equipment (PPE), such as a mask. If required, it will be provided. CCfV follows the guidance of the IWK Health Centre and Nova Scotia Public Health.

Table of Study Procedures (Vaccine Naïve Participants)

A = Only participants in Day 0 & 28 vaccine schedule groups
B = Only participants in Day 0 & 112 vaccine schedule groups

Visits	**Screening Contact***	**Visit 1**	**Contact**	**Visit 2**	**Contact A**	**Visit 3 A**	**Visit 3 B**	**Contact B**	**Visit 4**	**Visit 5**
Days		**0**	**7**	**28**	**35**	**56**	**112**	**119**	**140**	**365**
Time (Minutes)	**15**	**60**	**10**	**45[A] 15[B]**	**10**	**15**	**45**	**10**	**15**	**15**
Informed Consent	X	X								
Medical History	X	X	X	X	X[A]	X[A]	X[B]	X[B]	X	X
Height & Weight; BMI		X								
Vital Signs		X		X[A]			X[B]			
Urine Pregnancy Test		X		X[A]			X[B]			
Blood Sample [A]		X		X		X[A]			X	X
Blood Sample [B]		X		X			X[B]		X	X
Randomization	X	X								
Vaccination		**X**		**X[A]**			**X[B]**			
15-minute wait		X		X[A]			X[B]			
Contact			X		X[A]			X[B]		
Receive Diary Card		X		X[A]			X[B]			
Review Diary Card			X		X[A]			X[B]		
Collect Diary Card				X		X[A]			X[B]	
Acceptability Questionnaire						X[A]			X[B]	

***** The informed consent can be obtained electronically and the medical history including current medications can be collected and reviewed over the phone at the screening contact. Once eligibility is confirmed you will be randomized and scheduled for your vaccine visit. Or all these activities can occur at Visit 1.

Table of Study Procedures (Vaccine Exposed Participants)

A = Only participants in Day 0 & 28 vaccine schedule groups
B = Only participants in Day 0 & 112 vaccine schedule groups
Day 0 = Date the COVID-19 Vaccine was received in Public Health program

Visits	**Screening Contact***	**Visit 1**	**Contact A**	**Visit 2 A**	**Visit 2 B**	**Contact B**	**Visit 3**	**Visit 4**
Days		**Day 0 + 28**	**Visit 1 + 7**	**Day 56 (Visit 1 +28**	**Day 0 + 112**	**Visit 2[B] + 7**	**Day 140 (Visit 2[B] + 28)**	**Day 0 + 365**
Time (Minutes)	**15**	**30-60**	**10**	**45**	**45**	**10**	**15**	**15**
Informed Consent	X	X						
Medical History	X	X	X[A]	X[A]	X[B]	X[B]	X	X
Height & Weight; BMI		X						
Randomize to Dose 2	X	X						
Vital Signs		X[A]			X[B]			
Urine Pregnancy Test		X[A]			X[B]			
Vaccination		**X[A]**			**X[B]**			
Blood sample [A]		X		X[A]			X[A]	X
Blood sample [B]		X			X[B]		X[B]	X
15-minute wait		X[A]			X[B]			
Receive Diary Card		X[A]			X[B]			
Review Diary Card			X[A]			X[B]		
Collect Diary Card				X[A]			X[B]	
Acceptability Questionnaire				X[A]			X[B]	X

***** The informed consent can be obtained electronically and the medical history including current medications can be collected and reviewed over the phone at the screening contact. Once eligibility is confirmed you will be randomized and scheduled for your vaccine visit. Or all these activities can occur at Visit 1.

What are the burdens, harms, and potential harms?

Most people don't have any serious side effects from vaccines. The most common side effects are injection site reactions such as pain, swelling and redness. These are usually mild and go away quickly on their own.

The most common side effects after vaccination are mild. They include:

- Pain, swelling, or redness at the injection site
- Mild fever or chills
- Feeling tired
- Headache
- Muscle and joint aches

Most common side effects are a sign that your body is starting to build immunity (protection) against a disease.

Serious side effects from vaccines are extremely rare. For example, if 1 million doses of a vaccine are given, 1 to 2 people may have a severe allergic reaction. Other serious reactions may involve an immune reaction against the nervous system (Guillain-Barre syndrome).

The side effects seen in clinical trials for the vaccines used in the study include:

Pfizer-BioNTech Vaccine

The most frequent reported adverse reactions (side effects) after any dose were: injection site pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%) and fever (14.2%) and were usually mild or moderate in intensity and resolved within a few days after vaccination.

Moderna Vaccine

The most frequently reported adverse reactions (side effects) after any dose were: pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), muscle pain (61.5%) and chills (45.4%). The majority of local (injection site) and systemic (general) adverse reactions had an average duration of 1 to 3 days.

Overall, there was a higher reported rate of reactions in younger people; the incidence of axillary swelling/tenderness, fatigue, headache, muscle pain, joint pain, chills, nausea/vomiting, fever was higher in adults 18 to 64 years of age than in those 65 years of age and above. Reactions were also

more frequent after the second dose, compared to the first one, including severe local and systemic adverse reactions.

Other possible risks of being in this study:
As in any research study, your health status will be checked carefully so that any unexpected reaction can be identified. The study doctor is trained to take the right measures to reduce risks and limit any discomforts you may experience.

Ask the study staff if you have questions about the signs or symptoms of any side effects that you read about in this consent form. This is not a complete list of possible side effects. You may experience some different ones. The study staff may provide further information about possible side effects.

It is very important that you tell the study staff about any health problems you experience even if you think they were not caused by the vaccine. If a serious health problem occurs – for example, one that requires you to go to the hospital – you or a family member must tell the study doctor as soon as possible.

There is little information on using a different second dose of a COVID-19 vaccine. It is possible that it won't be as effective as using the same vaccines for both doses. It is also possible that the second vaccination may not provide a high enough immune response. If this occurs, you will be contacted to receive a booster dose.

Enhanced Disease
With some virus infections, individuals who have previously been vaccinated have experienced more severe disease when they are exposed to the virus in the community. This vaccine-associated disease enhancement has not been observed with this vaccine in studies done in animals or in any COVID-19 clinical trials or in the public health vaccine programs so far, but is still a theoretical possibility. You will be monitored very carefully if you become infected with the novel coronavirus (SARS-CoV-2) after you receive the study vaccine.

Allergic Reaction
As with any vaccination, there is very rare possibility of an allergic reaction with sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing. A more severe form of allergic reaction, anaphylaxis can occur, which may be serious, life-threatening or fatal. If such a reaction occurs, it is usually almost immediately after the vaccination. This is why we require that you remain in the clinic on the site for 15 minutes so that we can provide immediate medical attention if needed. The study staff are fully trained and equipped to deal with this unlikely event.

Blood sampling
When giving blood, you may have pain or tenderness, bruising, or rarely, an infection at the spot where the needle is inserted. Fainting or dizziness can occur after a needle stick, but this is uncommon.

Pregnancy
The safety and efficacy of the authorized vaccines in pregnant women have not yet been established. Use of these vaccines in pregnant women should be based on an assessment of whether the benefits of vaccination outweigh the potential risks. They may expose the unborn baby to unknown risks including the possibility of birth defects. If you are pregnant or if you intend to have a baby while you are in the study, you cannot participate.

Tell the study doctor if you are pregnant. In case of pregnancy, you will not be discontinued from the study. If you become pregnant after receiving your first dose but before receiving your second dose, you will not be given your second dose. You will still take part in the other study procedures be followed for safety assessment (and may be followed for immunogenicity assessment, if applicable) until the delivery of the baby.

Call the study staff right away if you have any side effects that you think are serious or if you have any signs or symptoms of COVID-19 infection.

What are the potential benefits?
There may be no additional direct medical benefit to you for participation in this clinical study. The vaccines you are receiving are authorized vaccines in Canada. You are expected to receive protection against COVID-19. You may receive the second dose of vaccine earlier in the study than if you got vaccine in the community, if you are randomized to a shorter interval study group. Your participation may help future patients and will help public health decision makers better understand different schedules for COVID-19 vaccines.

What alternatives to participation do I have?
Your alternative is to not take part in this study. You can choose to receive the authorized vaccine when available for your age group through public health. The vaccination rollout in Nova Scotia changes regularly as vaccine becomes available. The anticipated time that vaccine will be available is listed on the government website: https://novascotia.ca/coronavirus/vaccine/. Since the schedule changes regularly, study staff will update you about the current stage of the vaccine rollout at each study visit.

Anticipated appointment availability by age group

Age group	Anticipated start for booking appointments
80 and older	March 2021
75 to 79, 70 to 74, 65 to 69, 60 to 64, 55 to 59	April 2021
50 to 54, 45 to 49, 40 to 44, 35 to 39, 30 to 34, 25 to 29	May 2021
20 to 24, 16 to 19	June 2021

What are my research rights?

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator, the research doctor, the study sponsor or involved institutions from their legal and professional responsibilities.

If you have any questions at any time during or after the study about research in general or your rights as a participant, you may contact the Research Office of the IWK Health Centre at 902-470-7479, Monday to Friday between 8 am and 4 pm.

Can I withdraw from the study?

Yes, you can agree to be in the study now and change your mind at any time and for any reason. You can withdraw from the study and your decision will not affect your regular care.

You can talk to the study doctor/staff first before making this decision.
The study doctor/staff and the study sponsor also have the right to remove you from the study at any time, with or without your agreement. These decisions will be made if:

- It is in your best medical interest to stop
- You do not follow the study staff's instructions
- The study is canceled
- You no longer meet the eligibility criteria

The study doctor/staff will discuss with you the reasons for removing you from the study, other treatments or research options, and plans to follow up with you for side effects, if needed.

Your collected samples will continue to be analyzed as described in this form unless you specifically ask for them to be destroyed. This is to protect the quality of the study.

Will the study cost me anything, and, if so, how will I be reimbursed?

There are no costs to you to be in the study. The sponsor will obtain the study vaccine from public health and pay for tests that are part of the study. As reimbursement for out-of-pocket expenses such as travel costs to and from study visits, you will receive $50 per visit for each visit and a parking pass at the end of each visit (if you park in the IWK parking garage).

This will be paid out by gift card or cheque after the study visits.

You will receive $50.00 and a pre-paid parking pass per visit for any unscheduled illness visits that are required. This will be added to the next scheduled payment.

Payment will be made by cheque through Dalhousie University. You will be asked to sign a form to receive the cheque. If for any reason you do not complete the study, you will be compensated for the total number of visits completed up to that time and you would receive a cheque for the appropriate amount approximately 6 weeks after signing the form.

Are there any conflicts of interest?

There are no known conflicts of interest on the part of researchers and/or CCfV. Funding from the study funder will cover the costs of conducting the study at CCfV, and the study nurses and research assistants will be compensated for the time and expenses to conduct the study.

What about possible profit from commercialization of the study results?

If the study results indicate a change in licensing recommendations after the study is completed, you and CCfV will not receive any of the financial benefits.

How will my privacy be protected?

Your privacy and confidentiality will be respected. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. Your personal information or information that could identify you will not be revealed without your express consent unless required by law. If facts become known to the researchers which must be reported by law to public health authorities or legal authorities, then your personal information will be provided to the appropriate agency or authority. You may contact the study doctor to consult your study file and correct any errors. However, you may not be able to review some of your records related to the study until after the study has been completed.

If you decide to participate in this study, the study doctor and research team will use information about you as described in this consent form. This may include your name, address, phone number, email, medical history, date of birth, ethnicity, and information from your study visits. Studies involving humans now routinely collect information on race and ethnic origin as well as other

characteristics of individuals because these characteristics may influence how people respond to different medications. Providing information on your race or ethnic origin is voluntary.

You will be given a unique study number as a participant in this study. This number will not include any personal information that could identify you (it will not include your name, Personal Health Number, Social Insurance Number, or initials, etc.). The number will be used on any research-related information and samples that go outside the study site so that only CCfV doctors and study staff will know your personal information. The list that matches your name to the unique study number that is used on research-related information will not be removed or released without your consent unless required by law.

Who will have access to my data?

Research records, personal and health information or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the Sponsor, the Funders, representatives from the IWK Health Centre Research Ethics Board, and Health Canada and the Food & Drug Administration (FDA) to make sure that the study is being done properly. They can only see your personal information with the study doctors or staff nearby and cannot take anything away from the study site.

If the results of this study are published, your identity will remain confidential. Only de-identified information collected during this study will be used in analyses and will be published/presented to the scientific community at meetings and in journals. This de-identified information may also be used as part of a submission to regulatory authorities around the world to support the approval of vaccines used in this research.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of researchers and others to protect your privacy. You may take away your permission to use and share health data about you at any time by contacting the study doctor. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after that date; however, health data about you that has already been gathered will still be used in a nonidentifying form and given to others as described in this form.

Your study records, including confidential information collected during the study, will be kept in a secure location for at least 25 years after study completion, as required by Canadian clinical trial regulations. Your study specimens will be retained for up to 10 years by the study sponsor.

Your family physician will be notified of your participation in the study so that your study doctor and your family doctor can provide proper medical care, if you provide consent for us to do this.

What will happen to your samples?

Your samples will be processed and stored at the CCfV laboratory in Halifax, NS. In addition, samples will be sent to the other CIRN reference lab network (Reference Laboratory Network) laboratory in Toronto at Public Health Ontario (PHO). Additional testing will also be done at laboratories at the University of British Columbia (UBC) and Harvard Medical School in Boston, Massachusetts, USA. The study sponsor will not assess information about your genetic make-up as part of the main study. All study-related samples will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. These samples may be retained for up to 25 years by the study sponsor.

Future research on your samples:

Your leftover samples collected during the study can be very useful for additional research not related to the study such as the development and validation of new assays for measuring the effectiveness of vaccines. You can withdraw your consent at any time. In that case, samples will be destroyed and data already available will be anonymized unless otherwise required by applicable laws. Anonymized means all information that can be linked to you will be removed from your data. Your data and samples may be stored for up to 25 years after the end of the study. These samples will be stored at CCfV and Dalhousie laboratories in Halifax, NS. You can indicate on the signature page of this consent form if you agree to this testing or not.

How will I be informed of study results?

After all study participants have completed the study (which may be some time after you have completed your participation in the study), the Sponsor will analyze the data and offer you a summary of the study results that are understandable to the general public. The summary will not include individual results or information that can identify you or any other study participant. The summary may be made available to you through a study participant web portal which you can choose to access or through certain local and/or national websites.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law and Health Canada requirements. These websites will not include information that can identify you. At most, these websites will include a summary of the study results. You can search this website at any time.

Contact for future CCfV studies:

You will be asked at the end of the study if we can contact you for future studies for you at the Canadian Center for Vaccinology. If you agree to be contacted, it does not mean that you have to take part in future related studies. If you do not want to be contacted we would like to know why. We will record your answer if you choose to give one. If you wish to be contacted, we will ask you to initial the signature page of this form to indicate this, and reconfirm this when you have completed the study. If you still wish to be contacted at the end of the study, we will collect information that would include your names, address, phone number and dates of birth, which we

would store in a secure area separate from the study data. If you indicate you agree today and change your mind later, it is not a problem and will not impact your care in any way.

What if I have study questions or problems?

If you have any questions, please call the Research Coordinator – Yasaswini Palukuru at 902-470-8182 or yasaswini.palukuru@iwk.nshealth.ca. You can reach her Monday to Friday between the hours of 8 am and 4 pm. If you are calling after 4 pm, on the weekend, or on a holiday, please call **902-476-8837** to reach the on-call study nurse.

If you have an urgent study matter, you may also reach Dr. Langley by calling the IWK Health Centre at 902-470-8888 and asking for her to be paged.

In the event that participation in this study leads to any serious reactions or events, please contact your study nurse or coordinator as soon as possible. The matter will be reviewed with you and Dr. Langley, who will assist you in obtaining appropriate medical care.

Study Title: Immunogenicity and adverse events following immunization with alternate schedules of authorized COVID-19 vaccines in Canada: **MOSAIC** study (**M**ix and match of the second c**O**vid-19 vaccine dose for **SA**fety and **I**mmunogeni**C**ity)

Participant's Consent:

The study has been explained to me. I have read or had read to me all pages of this information and consent form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I had enough time to decide whether I should take part in the study. I understand the nature of the study and I understand the potential risks. I understand that my personal and medical information will be used as described in this form, and that my samples will be used as described in this form. I understand that I have the right to withdraw from the study at any time without affecting our care in any way. I have received a copy of the Information and Consent Form for future reference. I freely agree to participate in this research study.

Name of Participant: (Print) _____

Signature of Participant: _____

Date: _____ Time: _____

I would like to receive a copy of the study results when available. Circle: **Yes or No: Initial___**

I agree that my family doctor may be told of my study participation. Circle: **Yes or No: Initial___**

I agree to the use of my samples for future scientific research as described in this consent form, in addition to the testing required for this study. Circle: **Yes or No: Initial___**

I agree to be contacted and given information about future studies. Circle: **Yes or No: Initial___**

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY

I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study.

Name (Print): _____ Position: _____

Signature: _____ Date: _____ Time: _____

STATEMENT BY PERSON OBTAINING CONSENT

I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time from participating.

Name (Print): _____ Position: _____

Signature: _____ Date: _____ Time: _____