



## INFORMATION & CONSENT FORM

**RESEARCH TITLE:** A Randomized, Observer-Blind, Dose-Escalation Phase 1/2 Clinical Trial of COVAC Vaccines in Healthy Adults

**SHORT TITLE:** A randomized study, assessing the safety and immunogenicity of a COVID-19 vaccine in healthy adults

**PROTOCOL NUMBER:** COVAC-001

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**FUNDER:** University of Saskatchewan  
Vaccine and Infectious Disease Organization-International Vaccine Centre (VIDO-InterVac)

**SPONSOR:** University of Saskatchewan  
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## **Introduction**

You are being asked to take part in this research study to assess the safety and ability of an investigational study vaccine to generate an immune response against the virus causing COVID-19 disease. You can decide if you want to take part in this study or not. Your choice will not change the quality of care that you will receive outside of this study. Please take time to read the following information about the study. Feel free to ask the study staff any questions that you may have.

Informed consent means agreeing to take part in a research study, but only when you fully understand what this means for you. You sign this informed consent form only if you agree to take part in this study. Signing the form shows that you have understood what this means for you and that you want to take part. Before you decide to join a study, you can discuss everything you heard from the study staff with your family, friends, and other people you trust. Consent is an ongoing process and we will verbally reconfirm that you want to continue participating in the study at each follow-up contact.

A Phase 1 study is a trial of an investigational vaccine that is tested in a small group of people for the first time to evaluate its safety and identify side effects. A Phase 2 study builds on the Phase I study data to increase the number of study participants with additional safety data and to measure the body's immune response to the vaccine. A Phase III study uses the data from Phase 1 and 2 studies and is given to even more people to see if the vaccine works to protect people against the infection. After a Phase 3 study a vaccine can be submitted for Health Canada approval for use in the general public.

This is a Phase 1/2 COVID-19 vaccine study. The study has been approved by Health Canada but the study vaccine has not yet been approved for sale or widespread use. A research study is outside the normal care that you would receive and has increased monitoring than would normally occur. This consent form is for Phase 1 only.

## **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 (WHO) quickly declared COVID-19 a pandemic due to the rapid increase in the number of cases globally.

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, seniors, people with weakened immune systems, and people with underlying medical problems like asthma, heart problems or diabetes, 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 potential 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.

VIDO-InterVac has developed a vaccine called COVAC-2. The study vaccine contains a portion of the SARS-CoV-2 spike protein, called S1. The spike protein is the part of the virus that is responsible for attaching to the surface of host cells. COVAC-2 contains a Squalene-in-Water Emulsion (SWE) adjuvant. An adjuvant is a compound that is added to a vaccine to help the vaccine produce a better immune response. The SWE adjuvant is similar to another adjuvant, MF59, that is found in influenza vaccines and MF59 containing vaccines been given to millions of people around the world. The vaccine is expected to stimulate the body to make antibodies against the S1 protein. The antibodies will recognize the viral spike protein if the body is exposed to the virus and prevent COVID-19 illness. In animal studies the immune response generated by the COVAC-2 vaccine was able to protect the vaccinated animals against a severe SARS-CoV-2 infection. This consent form is for the Phase 1 portion of the study using the COVAC-2 vaccine.

**How will the researchers do the study?**

In Phase 1, a total of 108 healthy adults will be enrolled at the Canadian Center for Vaccinology (CCfV) located at the IWK Health Centre in Halifax, NS.

The study is looking at 3 different dosages of the study vaccine given as two injections (28 days apart) and compared to a placebo (inactive solution). The dosages will be composed of either a low (25µg), medium (50µg), or high (100µg) dose of S1 protein antigen.

A placebo is a saline solution (water and salt) that does not contain the vaccine.

This is an observer blinded study. This means that neither the doctor nor you will know or be able to choose which vaccine group you receive. The study nurse who gives that vaccine will know which vaccine you receive. You will only be told which group you were in 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.

This is a randomized study. Randomized means that your vaccine group will be chosen at random (like rolling a dice). You may be put into one of these three dose groups. Each participant has 2 to 1 chance to receive the study vaccine compared to the placebo.

A total of 108 participants will be vaccinated in three steps.

**Step 1 – Low Dose: 36 Participants**

Step	Age (years)	Group	Number per Group	Dose
1	18-54	A	8 participants	2 injections (low dose)
		B	4 participants	2 injections placebo
	55-69	G	8 participants	2 injections (low dose)
		H	4 participants	2 injections placebo
	70+	M	8 participants	2 injections (low dose)
		N	4 participants	2 injections placebo

**Participants will enroll in Step 1:**

1. Participants (age 18-54) will be randomly assigned into Groups A or B.
2. To start, a maximum of 3 participants will be enrolled.
3. After the Day 7, if there are no safety concerns for the first 3 participants then the remaining participants in Groups A and B will continue to enroll.

4. A special committee of experts (Data Safety Management Board – DSMB) external to the study team will review the data arising from the study. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.
5. If there are no concerns, the visits for the second injection will continue for the 18-54 age group in Step 1.
6. If there are no concerns after the second injection for Groups A and B, the 55-69 age group and the 70+ age group in Step 1 will start.
7. Participants (age 55-69) will be randomly assigned into Groups G or H and participants (age 70+) will be randomly assigned to Group M or N.
8. To start, a maximum of 3 participants will be enrolled within each age group.
9. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.
10. After the Day 7, if there are no safety concerns for the first 3 participants then the remaining participants in Groups G and H and Groups M and N will continue to enroll.
11. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.
12. If there are no concerns, the visits for second injection will continue for Groups G and H and Groups M and N.

**Step 2 – Medium Dose: 36 Participants**

Step	Age (years)	Group	Number per Group	Dose
2	18-54	C	8 participants	2 injections (medium dose)
		D	4 participants	2 injections placebo
	55-69	I	8 participants	2 injections (medium dose)
		J	4 participants	2 injections placebo
	70+	O	8 participants	2 injections (medium dose)
		P	4 participants	2 injections placebo

**Participants will enroll in Step 2:**

1. Participants (age 18-54) will be randomly assigned into Groups C and D.
2. To start, a maximum of 3 participants will be enrolled.
3. After the Day 7, if there are no safety concerns for the first 3 participants then the remaining participants in Groups C and D will continue to enroll.
4. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.
5. If there are no concerns, the visits for second injection will continue for the 18-54 age group in Step 2.
6. If there are no concerns after the second injection for Groups C and D, the 55-69 age group and the 70+ age group in Step 2 will start.
7. Participants (age 55-69) will be randomly assigned into Groups I and J and participants (age 70+) will be randomly assigned to Groups O and P
8. To start, a maximum of 3 participants will be enrolled within each age group.
9. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.
10. After the Day 7, if there are no safety concerns for the first 3 participants, then the remaining participants in Groups I and J and Groups O and P will continue to enroll.
11. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.
12. If there are no concerns, the visits for second injection will continue for the 55-69 age group and the 70+ age group in Step 2.

### Step 3 – High Dose: 36 Participants

Step	Age (years)	Group	Number per Group	Dose
3	18-54	E	8 participants	2 injections (high dose)
		F	4 participants	2 injections placebo
	55-69	K	8 participants	2 injections (high dose)
		L	4 participants	2 injections placebo
	70+	Q	8 participants	2 injections (high dose)
		R	4 participants	2 injections placebo

#### Participants will enroll in Step 3:

1. Participants (age 18-54) will be randomly assigned into Groups E and F.
2. To start, a maximum of 3 participants will be enrolled.
3. After the Day 7, if there are no safety concerns for the first 3 participants then the remaining participants in Groups E and F will continue to enroll.
4. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.
5. If there are no concerns, the visits for second injection will continue for the 18-54 age group in Step 3.
6. If there are no concerns after the second injection for Groups E and F, the 55-69 age group and the 70+ age group in Step 3 will start.
7. Participants (age 55-69) will be randomly assigned into Groups K and L and participants (age 70+) will be randomly assigned into Groups Q and R.
8. To start, a maximum of 3 participants will be enrolled within each age group.
9. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.
10. After the Day 7, if there are no safety concerns for the first 3 participants, then the remaining participants in Groups K and L and Groups Q and R will continue to enroll.
11. If there are no concerns, the visits for second injection will continue for the 55-69 age group and the 70+ age group in Step 3.
12. The DSMB will conduct safety analysis of data and ensure there are no safety concerns.

#### How do I know if I can be in the study?

You can take part in this study if:

1. You are at least 18 years of age or older.
2. You are available for all the study visits.
3. You are in good health.
4. You have never tested positive to COVID-19.
5. Your physical examination and blood test at the screening visit are within normal limits.
6. You agree to practice adequate contraception (birth control) if you are of child-bearing potential (able to get pregnant).

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

#### What will I be asked to do?

Your participation in the study will involve 11 planned visits to CCfV over approximately 12 months. This will include a screening visit to make sure you are eligible to participate, two vaccination visits (Day 0 and Day 28), and eight follow-up visits.

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 signed copy of it to keep. We will verbally reconfirm that you want to continue participating in the study at each follow-up contact.

If you consent to participate in the study then there will be a screening visit to make sure you are eligible to take part in the study. The screening visit can occur up to 30 days before the first vaccine visit. The time commitment for the screening visit will be approximately 1 hour.

At the screening visit, you will be asked about your medical history; such as previous allergies, illnesses, and all medications you are currently taking to ensure that you are eligible to participate in the study. If you are a female who can get pregnant, you will be asked about your method of birth control. You will have a urine sample taken to confirm that you are not pregnant.

If you are enrolled in this study then it will be your responsibility to attend your scheduled appointments, to keep the study staff informed of any problems or side effects that you experience while in the study and report any new medications you are taking, to fill out the diary you are given and return to the study staff, to use an acceptable method of birth control (if applicable), and to ask the study staff any questions as you think of them.

**Table of Procedures**

Visit	Screening Visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10
Study Day	Day -30 to 0	Day 0	Day 7	Day 14	Day 28	Day 35	Day 42	Day 56	Day 90	Day 120	Day 365
Time (Minutes)	45-60	60-120	15-30	15-30	60-120	15-30	15-30	15-30	15-30	15-30	15-30
Informed Consent	X										
Medical History	X	X	X	X	X	X	X	X	X	X	X
Review Medications	X	X	X	X	X	X	X	X	X	X	X
Physical Exam & Vital Signs	X	X	X	X	X	X	X	X	X	X	X
Urine Pregnancy Test (if applicable)	X	X			X						
Blood Sample Approx. (mL)	X (16)	X (40)	X (40)	X (50)	X (50)	X (50)	X (50)	X (10)	X (10)	X (40)	X (40)
Urine Sample	X		X	X	X	X	X				
Vaccination		X			X						
30 minute wait		X			X						
Receive Diary		X		X	X	X					
Return Diary			X	X	X	X	X				

\* If you are 1 of the first 3 participants enrolled in Steps 1, 2, and 3, you will receive a phone call from the study staff 48 hours after you receive the first vaccination. This phone call will take approximately 5-10 minutes.

## Screening Visit Procedures

**Blood Samples** – You will be asked to provide a blood sample at the screening visit to see if you are eligible for study. The blood tests will be a CBC (complete blood count, including your hemoglobin), kidney, and liver function (ALT, AST, BUN, and creatinine) to see if they are in the normal range.

You will be tested for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and the Human Immunodeficiency Virus (HIV). If the results of your blood tests are positive they must be reported to public health officials.

The total amount of blood collected at this visit is 16 mL (approximately 3 teaspoons).

**Urine Sample Collection** – A urine sample will be collected for routine laboratory tests to check for any changes in your overall health at the screening visit and during the study (at Days 7, 14, 28, 35, and 42).

We will tell you the results of the screening process and whether you are eligible to participate in the study or not. If any of the screening results are outside the normal range you will be informed and you will not be able to take part in the study. The study doctor will meet with you to explain the results if they are outside the normal range. The screening results may identify conditions or illnesses that you were not aware of. This information could be concerning to you and might have implications for your health or as with any pre-existing health condition, your ability to get additional private health insurance (i.e. beyond Canadian Medicare) in the future. We will ensure that you have appropriate follow up care and if you give us permission, we will notify your family physician.

**Pregnancy Test/Birth Control** – The possible effects of the study vaccine on the embryo, fetus, or nursing infants are unknown at this time. Therefore, there may be unknown risks to you, the embryo, fetus, or nursing infant if you are or become pregnant during the study. There may also be unknown risks if you are breastfeeding during the study.

A urine pregnancy test will be taken at screening to confirm that you are not pregnant and then follow-up urine pregnancy tests will be done before each vaccination on Day 0 and Day 28.

You cannot participate if you are, or plan to become pregnant, or if you are, or plan to start breastfeeding. All female participants able to bear children must use a highly effective method of contraception from 30 days prior to vaccination (Day 0) up to at least 180 days after the last study vaccination (Day 28).

Effective contraception methods are:

- Combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation:
  - Oral;
  - Intravaginal;
  - Transdermal;
- Progestogen-only hormonal contraception associated with inhibition of ovulation:
  - Oral;
  - Injectable;
  - Implantable;

- Intra-uterine device (IUD) with or without hormonal release;
- Vasectomised partner, provided that this partner is your sole sexual partner and that the vasectomised partner has received a medical assessment of the surgical success;
- Credible self-reported history of heterosexual abstinence prior to and for at least 180 days after the last study vaccination;
- Female partner.

No one method of contraception is 100% effective. There may be a possibility that the study drug may lessen the effectiveness of a hormonal contraceptive agent. You should immediately inform your study doctor if you plan to change your method of birth control during the course of the study or if you become pregnant.

If you become pregnant during the study, the study doctor or study staff will ask you questions about your pregnancy and follow the outcome. This information will be reported to the Sponsor without your name or any personal identifiable information.

**Medical History** – We will ask you questions about your previous medical history and any medication that you are taking to confirm that you are eligible to take part in the study.

**Physical Exam** – A physical exam will be done at the screening visit or on Day 0. The purpose of the physical examination is to assess your overall health and body systems. A physical exam includes examining your heart, lungs, abdomen, eyes, ears, nose, and throat. As well as assessing other body systems such as the nervous and musculoskeletal (muscles and bones) systems. Targeted physical exams may occur at other study visits, if deemed necessary.

**Vital Signs** – The research staff will measure your blood pressure, heart rate, breathing rate, and temperature at the screening visit and each follow-up study visit. In addition, your height and weight will be measured at screening.

**Demographic Information** – We will collect information such as your date of birth, sex at birth, gender, race, and ethnic background.

## **Follow-up Study Visit Procedures**

If you are eligible and still agree to be in the study, we will schedule the vaccination visit. The following procedures will be done at the follow-up visits:

**Medical History** – At each visit, the study staff will ask you questions about any changes in your health. We will also ask if you have taken any medications/received any vaccines.

**Blood Samples** – You will be asked to provide a blood sample at all the follow-up study visits. Some of the blood will be used to do common blood tests to make sure yours are within a normal range (approximately 10 mL or 2 teaspoons/sample); and some of the blood will be tested 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) (approximately 10-40 mL or 1 to 2 ¾ tablespoons/sample).

**Vaccinations** – You will be assigned to one of the study groups to receive either the two doses of study vaccine or two doses of placebo. The first dose will be given at Day 0 and the second dose will be given at Day 28. The vaccine or placebo will be given in the upper arm (deltoid) muscle of your non-dominant arm. After the vaccination, you will be asked to stay at the clinic for at least 30 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. We may try to contact you to confirm follow-up visits or if you do not show up at a scheduled visit.

We will verify with you at each visit 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 be provided with a diary during the study. For the first seven days (including Day 0) after each vaccination, you will be asked to carefully record (at roughly the same time each evening, once per day for seven days) the following information in the diary:

- Oral temperature, taken with the thermometer provided. You should not take your temperature immediately after drinking a hot or cold beverage or after smoking;
- Any redness and swelling, measured with the help of a special ruler, and/or any pain or other reactions at the vaccination site;
- Any general symptoms you experience, including drowsiness, fever, nausea, diarrhea, vomiting, generalized muscle aches, and headache.
- Any other changes in your health or doctor visits until Day 28 after each vaccination.

You will be asked to return the diary card at each visit and it will be reviewed with you.

At each study visit we will ask questions to see if you have any symptoms suggestive of COVID-19. We will provide instructions 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). If required, PPE will be provided. CCfV follows the guidance of the IWK Health Centre and Nova Scotia Public Health.

**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 new vaccine, COVAC-2, has not been given to people before; therefore little is known about the kind of reactions that might happen when given to humans.

The COVAC-2 vaccine has been tested in animals and has been found to be safe and immunogenic.

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, transverse myelitis).

### **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 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.

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.

Throughout this study, a Data Safety Monitoring Board (DSMB) will look at information about the health of the people taking part. Personal identifying information, like name or birthdate will not be provided to this Board, only anonymized data will be shared. If at any time the Board feels it is unsafe to continue the study, it might decide to pause or stop the study. The research staff will tell you any new information in a timely manner that could affect your willingness to take part.

### **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. 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 at least 30 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.

### **Placebo**

Since the placebo is like salt water, you will probably not have any reaction to it (other than discomfort related to the injection). However, this cannot be guaranteed.

### **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.

**If you have any immediate side effects that you think are serious, call 911 or proceed to the Emergency Department. Call the study staff to notify them right away.**

If you experience a serious adverse event, such as if you are hospitalized or have an emergency room (ER) visit for any reason, your medical records will be accessed to verify any diagnoses and establish potential causality. If you develop COVID-19 symptoms that require a swab to test for illness then the lab results will be obtained for your study records. By signing this consent form you are allowing this access.

### **What are the possible benefits?**

There may or may not be any direct benefit for taking part in this research study. If you are randomized to receive the study vaccine, it is possible that your body may produce antibodies to the novel coronavirus SARS-CoV-2. If the vaccine does not work or if you receive the placebo, you may not receive a health benefit. Information gained from this study will help in the development of a vaccine against COVID-19.

If the study vaccine is proven to be safe and effective then it will be made available to you if you were in the placebo group and wish to receive the study vaccine.

### **What alternatives to participation do I have?**

Recently, Health Canada approved two vaccines for the prevention of COVID-19. At this time in Nova Scotia the current vaccination plan is:

Phase 1 of the COVID-19 immunization plan runs from January to April and includes:

- a continued focus on immunizing front-line health-care workers who are closely involved in the COVID-19 response
- all staff, designated caregivers and residents in long-term care residential care residents and staff
- seniors living in the community who are 80 or older, followed by anyone 75-79
- health-care workers such as physicians, paramedics and home-care workers whose work involves direct contact with patients

Phase 2 is expected to begin in May and will include remaining health-care workers and essential workers.

Phase 3 will begin in summer and include all Nova Scotians who are not part of the Phase 1 and 2 priority groups.

Participation in this study will not prevent you from being vaccinated with the approved COVID-19 vaccine once the vaccination program is expanded to general population. Please inform your study doctor immediately if you are planning to receive the approved COVID-19 vaccine at any time during the study.

You do not have to participate in this study. This study is for research purposes only. You do not have to take part if you do not want to. Talk with your doctor about your options before you decide if you will take part in this study. The study doctor can advise you if you need more information.

### **Can I withdraw from the study?**

Taking part in this study is entirely your choice. You may decide not to enroll or you may withdraw from the study at any time. Your choice will not affect your care in any way.

Your participation in this study is voluntary. During the study, you will be informed as soon as possible of any new information on the vaccine that may affect whether you want to continue participating in the study. You may refuse to participate, or you may discontinue your participation at any time without explanation. If you refuse to participate or if you end your participation, you will not be penalized or lose any benefits to which you are otherwise entitled. If you decide to discontinue your participation, please tell the study staff; they will ask you to complete the final study visit. If you decide to leave the study, the information about you or your sample(s) that was collected before you left the study will still be used. No new information or samples will be collected without your permission.

The study doctor or a designated study staff member may end your participation, without your consent, based on their medical judgement. The Sponsor and/or the study doctor might decide to end your study participation if you are not following the study requirements. If you are withdrawn from the study by the study doctor or study staff, the reason for your withdrawal will be explained to you. In addition, the Sponsor or the regulatory authorities may stop the study.

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

There will be no costs to you to take part in this study. You will receive \$50/visit for the 11 scheduled in-person visits. A parking pass will be provided at the end of each in-person visit if you park in the IWK parking garage.

You will receive the reimbursement in the form of a gift card at each in-person study visit, or a cheque can be mailed to you. You will receive \$550 total if you complete all the study visits.

If you require an unscheduled visit as part of this clinical study due to illness or to repeat a blood test you will receive \$50 per visit.

Or if you prefer, payment can 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 will receive a cheque approximately 4-6 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?**

The study Sponsor (VIDO-InterVac) will be the owner of the study results. They plan to use the results, and may get patents, sell the drug in the future, or make profits in other ways. You and the researchers will not be paid any part of this.

**How will I be informed of study results?**

The overall study results and which vaccine you received can be made available to you once the study is completed and reported. This may take many months after the study has been completed. The results will be mailed to you if you request to receive them. You will be asked to initial the last page of this form indicating if you wish to receive the results. It will be important that you notify us if there is any change in your address, so we are able to contact you with the study results.

### **What are my research rights?**

Your signature on the form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator(s), sponsors, or involved institution(s) from their legal and professional responsibilities. 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. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive.

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 902-470-7879, Monday to Friday between 8 am and 4 pm.

### **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. The list that matches your name to the unique study number that is used on research-related information is kept at the study site securely and will not be removed and/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 will be inspected in the presence of the Investigator or their designate by representatives of the Sponsor, VIDO-InterVac, representatives from the IWK Health Centre Research Ethics Board, and Health Canada or other regulatory agency inspectors 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 that contain your personal information.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Information about this study will also be available on the Health Canada's Clinical Trials Database <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/health-canada-clinical-trials-database.html>. This website will not include information that can identify you. You can search this website at any time.

If the results of this study are published, your identity will remain confidential. It is expected that 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 drugs 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 may still be used 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 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 with your study samples?**

Your blood samples will be sent to VIDO-InterVac's laboratory or the CCfV laboratory for testing of the immune response against the SARS-CoV-2 virus. No testing will be done on your DNA or genetic material. The samples will be identified only by a study code and none of your personal information will be made available to these laboratories.

Collected samples may be stored for up to 15 years. Once the samples are no longer needed, they will be destroyed.

In addition, if you agree, your biological samples may be used by VIDO-InterVac for further research that may or may NOT BE RELATED to the disease or the vaccine under study. This testing will be done on anonymized samples (meaning that any identification linking you to the sample is destroyed). You will be asked if you agree to this on the final consent page. This testing is optional and does not affect your participation in the study.

#### **Contact for future studies**

You will be asked at the end of the study if we can contact you for future Canadian Center for Vaccinology (CCfV) studies. If you agree to be contacted, it does not mean that you have to take part in future 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 will include your name, address, phone number, email address and date of birth, which we store in a secure area. 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, contact the Research Nurse Coordinator, Pam MacIntyre, at 902-470-8948 or [pamela.macintyre@iwk.nshealth.ca](mailto:pamela.macintyre@iwk.nshealth.ca). You can reach the Research Nurse 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:** A Randomized, Observer-Blind, Dose-Escalation Phase 1/2 Clinical Trial of COVAC Vaccines in Healthy Adults

**Participant Consent**

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 understand the nature of the study and I understand the potential risks. I understand that my information and 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 my 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: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

I agree to have my leftover blood samples used by the Sponsor for further research that may or may NOT BE RELATED to the disease or the vaccines under study. I understand the testing will be done on anonymized samples (meaning that any identification linking me to the sample is destroyed).

YES       NO    **Initial**\_\_\_\_\_

I agree that the study staff has my permission to tell my primary care physician about my participation in this study.

YES       NO    **Initial**\_\_\_\_\_

I would like to receive a copy of the study results when available.

YES       NO    **Initial**\_\_\_\_\_

I agree to be contacted and given information about future studies.

YES       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: \_\_\_\_\_