INFORMATION & CONSENT FORM

RESEARCH TITLE:	Phase I/II Trial to Evaluate Safety, Tolerability, Immunogenicity of a Prophylactic Plasmid DNA Vaccine against SARS CoV-2 [Covigenix VAX-001] in Healthy Adults from 18 to <85 years of age
SHORT TITLE:	A Study to Test the Safety and Effectiveness of a COVID-19 Vaccine Candidate in Healthy Adults
PROTOCOL NUMBER:	ENTVAX01-101
RESEARCHERS:	
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FUNDER:	Entos Pharmaceuticals, Canadian Institutes of Health Research, Research Nova Scotia and Institute of Aging
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Introduction

You are being asked to take part in this research study. 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 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.

New vaccines need to be tested and then approved by health agencies. First the vaccine is tested in a laboratory. If it is safe, doctors test how well the vaccine works in studies with people. That is called a research study. Several research studies are needed to see if the vaccine is safe and useful when given to people. National health agencies look at the results of the studies. If they approve the vaccine, then it can be given to many people outside of research studies.

A Phase I study is a trial of an experimental vaccine that is tested in a small group of people for the first time to evaluate its safety and identify side effects. A Phase II 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 I and II studies and is given to even more people to see if the vaccine works to protect people against the infection. After a Phase III study a vaccine can be approved for use in the general public.

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 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 lung problems, heart problems or diabetes, have a higher risk of developing serious complications or dying from COVID-19. The World Health Organization (WHO) quickly declared COVID-19 as a pandemic due to the rapid increase in the number of cases globally. 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.

We are doing this study because researchers would like to develop a vaccine against COVID-19. Entos Pharmaceuticals has developed Covigenix VAX-001. It is a new DNA-based vaccine which causes some of your cells to make some of the COVID-19 virus proteins which your body then makes an immune response against them.

How will the researchers do the study?

A total of 72 adults between 18 to 54 and 65 to 84 years of age will take part in Phase 1 of this study at the Canadian Center for Vaccinology (CCfV) located at the IWK Health Centre in Halifax, NS.

The study is looking at 2 different dosages (low and high) given as two doses (Day 0 & 14) compared to a placebo (inactive solution). There are 2 steps to this study.

This is an observer blinded study. Neither the doctor nor you will know or be able to choose which vaccine you receive. Only the study nurse giving the vaccine will know 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.

This is a randomized study. Randomized means that your vaccine group will be chosen at random (like rolling a dice). The randomization for this study is 2:1 this means you are 2 times more likely to receive the vaccine than placebo.

A total of 72 individuals will be vaccinated. There will be 36 participants who are 18 to 54 years of age who will be enrolled with 12 participants in the low-dose group, 12 participants in the high-dose group and 12 in the placebo group. There will be 36 participants who are 65 to 84 years of age older who will be enrolled with 12 participants in the low-dose group, 12 participants in the high-dose group, and 12 participants in the placebo groups.

Study Groups

Step	Age	Group	Number per Group	Vaccine – 2 doses
1	18-54	1	12 participants	Low dosage
		2	12 participants	High dosage
		3	12 participants	Placebo
2	65-84	4	12 participants	Low dosage
		5	12 participants	High dosage
		6	12 participants	Placebo

Participants will be enrolled in a sequential manner (one step at a time), initially into Step 1 only, followed by Step 2. The reason is to examine any side effects participants may experience and to make sure the side effects are not severe, before enrolling older adults and before increasing the dosage of the vaccine. Safety data will be reviewed by a Data and Safety Monitoring Committee (DSMC) designated for this study. A DSMC is an independent group of scientists and vaccine specialists who are otherwise not involved in the study. If there are no safety concerns, the DSMC will give its approval to continue, and more potential participants will be recruited to join this study.

Participants will enroll in Step 1 then Step 2:

1. Participants (age 18-54) will be randomly assigned into Groups 1 or 3 (low dose vaccine or placebo).
2. To start a maximum of 3 participants will be enrolled, an hour apart.
3. After the Day 3 call if there are no safety concerns the remaining participants in Groups 1 and 3 will continue to enroll.
4. The DSMC will conduct safety analysis after 7 days of data and ensure there are no safety concerns.

5. If there are no concerns, the visits for Group 2 or 3 (high dose vaccine or placebo) in the younger age group will start to enroll and the low dose older adult groups will start. Participants (age 65-84) will be randomly assigned into Groups 4 or 6 (low dose vaccine or placebo).
6. They will enroll the same sequence as the younger group from low dose to high dose to dose 2.
7. The DSMC will conduct safety analysis after 21 days of data in the younger age group for dose 2 and ensure there are no safety concerns. If there are no concerns the high dose older age group will start.
8. The DSMC will conduct safety analysis after 42 days of data in the younger age group and ensure there are no safety concerns.
9. If there are no concerns, the Phase 2 study will start.

<u>You can take part in this study if</u>:

1. You are between 18-54 & 65-84 years of age.
2. You are available for all the study visits.
3. You are in good health.
4. Your body mass index (BMI) - a ratio measurement of your height and weight is not greater than 30.
5. Your physical examination and blood test at the screening visit is within normal limits.
6. You agree to practice adequate contraception (birth control) if you are of child-bearing potential (able to get pregnant). This include:
    a. Abstinence from penile-vaginal intercourse, when this is your preferred lifestyle,
    b. Hormonal contraceptives such as oral contraceptives (the pill), injectable, implants, patches or estrogen vaginal ring,
    c. Intrauterine device (IUD),
    d. Male partner sterilization (vasectomy) prior to the female subject's entry into the study, and this male is the sole partner for that subject,
    e. Male condom combined with a vaginal spermicide or female diaphragm, whether with or without a vaginal spermicide required for both male and female participants in the study.

    <u>Note</u>: Adequate contraception does not apply to participants of child-bearing potential with same sex partners, when this is their preferred and consistent lifestyle.

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

<u>What will I be asked to do?</u>

You will be in the study for about 12 months. You will have a total of 9 on-site visits and 1 phone call. The total time commitment is about 4-4 ½ hours.

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.

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 occurs within 14 days before the 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 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. You will have a blood sample taken.

Table of Study Procedures

Visits	**Screening**	**Visit 1**	**Visit 2**	**Visit 3**	**Phone Call**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**
Study Day	**Day -14**	**Day 0**	**Day 7**	**Day 14**	**Day 17**	**Day 21**	**Day 28**	**Day 42**	**Day 196**	**Day 379**
Time (minutes)	**30-60**	**60-75**	**10-15**	**60-75**	**5-10**	**10-15**	**10-15**	**10-15**	**10-15**	**10-15**
Informed Consent	X									
Medical History	X	X	X	X	X	X	X	X	X	X
Physical Exam* & Vital Signs	X	X		X						
Urine Pregnancy Test (if applicable)		X		X						
Throat/Nasal swab	X									
Blood sample	X	X	X	X		X	X	X	X	X
Blood Volume (mL)	*18*	*47*	*38*	*38*		*39*	*38*	*39*	*38*	*38*
Vaccination		**X**		**X**						
30-minute wait		X		X						
Receive Diary Card		X		X		X				
Review Diary Card			X		X		X			
Collect Diary Card				X		X		X		

*The physical exam will either be done at screening or Visit 1.

The first three participants enrolled in each group will be called at Day 3 to review their diary card information.

Screening Visit Procedures

Blood samples - You will be asked to provide a blood sample at the screening visit to test for common blood measurements (such as hemoglobin, kidney and liver function tests) to see if they are in the normal range and that you are eligible for the study. 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 show that you have a disease that must be reported to public health officials, the study doctor will

be obligated to report it. We will also ensure that you have appropriate follow up care. We will notify your family physician if you give us permission to inform them.

We will also test to see if you have any novel coronavirus (SARS-CoV-2) antibodies. If you test positive, you will not be eligible to receive the vaccine. The total amount of blood collected at the screening visit will be approximately 18 mL or approximately 4 teaspoons.

Swab - A nasal or throat swab will be taken to test for the novel coronavirus (SARS-CoV-2). If you test positive, you will not be eligible to receive the vaccine.

Physical Exam - A physical exam will be done either at the screening visit or at Visit 1 (before you receive the study vaccine). The purpose of the physical examination is to assess your overall health and body systems. Based on your history and findings at your physical examination, or if your health changes over time. You may be examined again at each follow-up study visit, to verify that you remain in stable condition.

Vital Signs - The research staff will measure your blood pressure, heart rate, breathing rate, and temperature. In addition, your height and weight will also be measured.

Demographic information - We will collect information such as your date of birth, gender and ethnic background.

Study Visit Procedures

If you are eligible after screening 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 and calls:

Blood Samples - If you are eligible to be in the study, you will be asked to provide a blood sample at all the follow-up on-site 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 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) (approximately 28 mL or 5 ½ teaspoons/sample).

As part of this study, we will test for another virus called cytomegalovirus (CMV), a virus most people have been exposed at some point by the time they are 50 years old. The CMV tests used in this study are for research use only, and we do not know the significance of a positive test. They are not standard clinical tests, and do not become part of your patient record.

Urine Pregnancy Test - Females who are able to get pregnant will provide a urine sample and have a pregnancy test done prior to receiving each vaccine. If the urine test is positive, you will not be eligible to receive the vaccine.

Vaccinations - The first dose will be given at Visit 1 (Day 0) and the second dose will be given at Visit 3 (Day 14). 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 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. During the study, we will make a follow-up phone call on Day 17 to ask about any symptoms you may be experiencing. The first three participants enrolled in each group

will be called at Day 3 to review their diary card information. We may also 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 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 also be asked to record 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. You will receive a second diary card to record any changes in your health or medication for days 7-13, 14-20 & 21-41.

You will be asked to avoid over the counter medications such as antipyretics (e.g., acetaminophen) and anti-inflammatory medications (e.g., ibuprofen, naproxen) in the 12 hours before getting the study vaccine. You can take these over the counter medications to treat fever or other adverse events after you receive the vaccination but please record the medication and why you used it on your diary card.

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.

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.

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 180 days after the last study 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. For male participants you must use an effective method of birth control or practice abstinence for 90 days after the last study vaccination.

COVID-19 Symptoms - If you develop symptoms suggestive of COVID-19 (fever, new or worsening cough, sore throat, runny nose and/or headache) you will be reviewed clinically, including a 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.

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). If required, it 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, Covigenix VAX-001 has not been given to people before; therefore little is known about the kind of reactions that might happen when given to humans.

There is a theoretical risk that the DNA from the vaccine could become part of your DNA. However, this has never occurred with any DNA vaccines that have been studied previously so this risk is considered to be low.

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).

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.

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.

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 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.

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.

Nasal or Throat swabs
A swab is like a small Q-tip that is inserted into the nostril or the back of your throat to take a small sample of mucus or cells. It takes a few seconds. It can be uncomfortable but is usually not painful.

Pregnancy and breastfeeding
The study vaccine has not been studied in pregnant women and may expose the unborn baby to unknown risks including the possibility of birth defects. If you are pregnant or breastfeeding 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. If you get pregnant during the study, you will remain in the study for follow-up. We will follow-up until the delivery of the baby.

In case of pregnancy, you will not be discontinued from the study. You will 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.

<u>What are the possible benefits</u>?
There may or may not be any direct benefit for taking part in this research study. If you are randomized to receive the vaccine, it is possible that your body will produce antibodies capable of binding 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.

<u>What alternatives to participation do I have</u>?
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. If you decide to stop your participation in the study for any reason, you simply have to inform the study staff. The data already collected will be analyzed and used as initially planned. If you leave the study for any reason, the study doctor may recommend that you come back for certain tests or examinations to check on your health.

In case you decide to stop your participation in the study and no longer authorize any further use of your personal data (consent withdrawal): your samples will not be used anymore and could be destroyed, but your coded data already collected will be kept as required by clinical regulations. Personal data include any information related to you such as name, contact and personal information, or your complete medical record. Coded data are your contact and personal information that are separated from medical information but can be linked by authorized people through a key.

Also, the study doctor may remove you from the study at any time. This could happen for many different reasons, for example, if there are concerns about your health, if you do not follow study instructions, or if the study gets stopped. If this happens, the study doctor will inform you and ensure that your participation in the study is stopped properly. The data and samples that have already been collected will be analyzed and used as initially planned.

Once you receive the vaccine, you must immediately notify the study doctor if you are hospitalized for any reason, have an illness consistent with COVID-19, or are tested for COVID-19. The study will be immediately stopped in case of any serious adverse event including those, which lead to hospitalization of a study subject and could be considered related to the vaccine and/or study procedures. You will be informed about the study suspension, the reason of the suspension, and necessary instructions will be provided to you. Once it is confirmed that it is safe for the study to continue, you will receive all available information allowing you to confirm your decision to continue or not to participate in the study.

Is the service/drug/intervention available after the study is complete?
If the vaccine is eventually approved for use, those in the placebo group will be given the opportunity to receive the vaccine.

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 the reimbursement in the form of a $50 gift card for each study visit and call. You will receive $500 total if you complete all the study visits. A parking pass will be provided at the end of each visit if you park in the IWK parking garage.

If you require an unscheduled visit due to illness or to repeat a blood test you will receive a $50 gift card 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?
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 I be informed of study results?
The group study results and your individual results 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 want 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 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, Entos Pharmaceuticals, 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. 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 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 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 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 with your study samples?

Your samples will be tested and stored at CCfV and Dalhousie laboratories in Halifax, NS. In addition, samples will be sent to a laboratory (PPD) in Highland Heights, Kentucky, 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 10 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. By signing this consent form you are agreeing to this and cannot opt out of this testing.

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, *(name to be inserted),* at *(number to be inserted)* or (*email to be inserted*). 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** *(number to be inserted)* **to reach the on-call study nurse.**

If you have an urgent study matter, you may also reach Dr. Halperin by calling the IWK Health Centre at *(number to be inserted)* and asking for him 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. Halperin, who will assist you in obtaining appropriate medical care.

Study Title: Phase I/II Trial to Evaluate Safety, Tolerability, Immunogenicity of a Prophylactic Plasmid DNA Vaccine against SARS CoV-2 [Covigenix VAX-001] in Healthy Adults from 18 to <85 years of age

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

I agree that the study staff may inform my family doctor of my study participation.
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: _____