INFORMATION & CONSENT FORM

RESEARCH TITLE:	A Phase 3, randomized, placebo-controlled, observer-blind, multi-country study to demonstrate the efficacy of a single dose of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above.
SHORT TITLE:	Effectiveness of the GSK investigational respiratory syncytial virus (RSV) vaccine in adults aged 60 years and above.
PROTOCOL NUMBER:	212494 (RSV OA=ADJ-006)
RESEARCHERS:	
Principal Investigator:	Dr. Joanne Langley, Pediatric Infectious Disease Specialist, IWK Health Centre
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FUNDER:	GlaxoSmithKline Inc. (GSK)
SPONSOR:	GlaxoSmithKline Inc. (GSK) 7333 Mississauga Road North Mississauga, ON, Canada L5N 6L4

Introduction

You are being asked to take part in the above research study. Your decision to take part in this study is voluntary. You are able to change your decision at any time. Your choice will not change the quality of care that you will receive outside of this study at the IWK Health Centre. Please take time to read the following information about the study and ask any questions that you have.

Before a new vaccine can be used in the general population, it needs to be tested and then approved. First, the vaccine is tested in laboratories. After that, doctors test how well the vaccine works in people. These are called clinical studies. National health agencies, like Health Canada, look at the results from clinical studies and decide if the vaccine is safe to use in people. If the vaccine is approved it can then be used in the general population.

Informed consent means by signing this form you agree to take part in this study. We encourage you to take your time and make sure you understand what is involved before you make your decision. You can discuss everything you heard from the study doctor or nurse with your family, friends and other people you trust (e.g. your family doctor).

Why are the researchers doing the study?

This study is being done to test a new investigational vaccine which has not yet been approved for general use by Health Canada. The vaccine being tested in this study is made to prevent infection from the respiratory syncytial virus (RSV) in older adults.

RSV is a cold-like germ that affects the airway and lungs. A person with a mild RSV illness may have a cold-like symptoms, such as a cough, sore throat, stuffy/runny nose, and fever. A person with severe RSV illness may have problems breathing. RSV infection can lead to more severe illnesses, such as a lung infection or respiratory failure.

Older adults have a higher risk of getting a severe RSV infection than younger adults. There is currently no specific treatment or vaccine against RSV in adults. Therefore, this investigational vaccine is being produced to protect older adults from RSV infection.

The investigational vaccine used in this study contains small parts of the virus (germ) that cannot cause RSV infection. These small pieces of the virus are recognized by your body's defense (immune) system and help produce antibodies. Antibodies help your body fight off germs.

The vaccine also has a substance called "adjuvant". The adjuvant improves the body's response to the vaccine.

The RSV vaccine that will be used in this study has been given to small numbers of people of 60 to 80 years of age. The findings showed that the vaccine was well tolerated. There may be other studies ongoing with this RSV vaccine at the time you are reading this document, including studies with people above 60 years.

This study is conducted by GlaxoSmithKline (also called "GSK"). GSK is a company that discovers, develops and makes vaccines, medicines and other healthcare products. The study team at the Canadian Center for Vaccinology will receive money from GSK to pay for the study.

The RSV vaccine being used in this study is investigational and is not available or approved for use outside of clinical studies.

How will the researchers do the study?

This study will enroll about 25,000 participants from several countries worldwide, including Canada. Approximately 40 participants will take part at the Canadian Center for Vaccinology located at the IWK Health Centre in Halifax.

If you take part in the research study, you will get one of two study products:

- RSV vaccine
  OR
- Placebo (salt water that will not affect you)

The group you get assigned to determines which product you will receive. You will have an equal 1 out of 2 (50%) chance of being assigned to either group. This is called randomization and is done using a computer. Neither you nor the doctor can choose or know which group you will be assigned to. This means that you and the doctor will not know whether you have received the vaccine or the placebo. Other people involved in the study, such as the person giving the vaccine, will know whether you are receiving the vaccine or placebo. You and the study doctor will only be told this information after the study is complete or in case of a medical emergency.

You can take part in this study if you are:

1. 60 years of age or above,
2. Medically stable,
3. Able and willing to comply with the requirements of the study.

Female and male participants will be recruited based on three age groups: 60-69 years, 70-79 years, and 80 years and above. Note that you may not enter the study if the age and gender group you belong to is full.

There are other criteria that we will review at the screening visit to determine if you are eligible for the study or not.

What will I be asked to do?

If you choose to participate in this study, you will need to sign the signature page at the bottom of this consent form. This indicates that you understand your involvement and the risks of participating in this study. You will receive a copy of the completed consent form to keep. Study staff will verbally reconfirm that you want to continue in the study at each follow-up visit.

The study activities are divided into 2 parts:

1. General study activities that will occur for all participants.
2. Activities that will happen only when you have cold-like symptoms.

General study activities:

Participation in this study involves 5 scheduled visits over a 3 year time period. This is for 3 RSV seasons when the virus is most present. Each year this ranges from October 1st to April 30th. In addition, there will be 3 contacts by study staff that will be done by phone or e-mail. During these contacts, we will ask questions about your health. The total estimated time commitment to participate in this study is 10.5 hours.

The following activities will be performed to make sure you can participate, continue to participate in the study, and evaluate the safety and the effect of the study vaccine. The procedures and activities that will be performed are detailed below:

Health Questions – You will be asked to provide information about your previous medical history and any vaccinations you have received. We will record any medication you have recently taken or are currently taking. At your first visit, we will also ask about your smoking history and perform a test to check your mobility. At the follow-up visits will ask if there have been any changes in your health since the last visit.

Demographics – We will collect your date of birth, sex at birth, race, ethnicity, geographical hemisphere location (Northern or Southern hemisphere), and type of residence (community or long-term care facility).

Physical Exam – You will have a physical exam on the day of vaccination (Visit 1) and at each visit before the start of RSV season (Visit 3 and Visit 4). This will include measuring your vital signs by checking your temperature, blood pressure, heart rate, breathing frequency, as well as listening to your breathing and measuring your oxygen blood level by placing a probe on your finger. We will measure your height and weight at Visit 1. Additional physical exams will be performed at other visits if the study doctor thinks this is needed for your health.

Blood Samples – You will need to give two blood samples at Visit 1 and Visit 2. Each blood sample is equal to about 20 mL (4 teaspoons).

Vaccination – You will receive the vaccine injection at Visit 1 in the muscle in your upper arm. You will be asked to wait for 30 minutes to monitor for any type of allergic reactions.

Diary Cards – You will receive a paper diary on the day of vaccination. In this diary, you will need to report any side effects that you experience and the names of any medications or other vaccinations you receive for up to 30 days post-vaccination.

If you are part of the subgroup, you will also be asked to write down if the following symptoms have occurred for 4 days after vaccination:

- Symptoms around the place of injection (pain, redness, and swelling at the place of injection)
- General symptoms (headache, tiredness, muscle pain, joint pain, and body temperature).

You will need to return the completed diary at your next visit.

Questionnaires – On the day of vaccination (Visit 1) and at each visit before the start of RSV season the following years (Visit 3 and Visit 4), you will be asked to complete 2 questionnaires about your health status and daily activities. The questionnaires are called "EQ-5D" and "SF-12".

The EQ-5D questionnaire asks you to rate your mobility, self-care, usual activities, pain/discomfort, anxiety/depression and overall health.

The SF-12 questionnaire asks you 7 questions about how you feel and how well you are able to do your usual activities.

It will take you approximately 20 minutes to complete both questionnaires.

You will be asked to complete an additional questionnaire at Visit 2 about your health and symptoms caused by RSV infection. This will take no more than 5 minutes to complete.

Participant Card – You will be given a card with information about the study. Keep this subject card with you at all times during the study. Show this card to any medical staff if emergency care is needed during the study. The medical staff can then contact your study doctor to ask about the vaccine you received, if needed.

Follow-up Contact – You will be contacted every 2 weeks during RSV season and once a month outside of RSV season. These contacts will be done by phone or e-mail.

If you have difficulties completing some study activities by yourself, you can choose a caregiver to help you. Your caregiver can be a friend or family member, for example. This person may help you to complete the diary card or questionnaires, receive phone calls, plan study visits, take swab samples, etc. The caregiver can only help you with the activities. They cannot make any decisions on your behalf. For example, when completing the diary card or questionnaire, the caregiver can only write down the information you ask them to complete.

What happens during each study visit and contact is detailed in the table below:

Visit Day	Visit Details
Visit 1 (Day 1) Time: 60-75 minutes	– Informed consent process – Health questions – Physical exam & vital signs – **Blood draw (20 mL)** – **Vaccination** & 30 minute wait – Receive diary – EQ-5D and SF-12 questionnaires
Visit 2 **(1 month after Day 1)** Time: 30-60 minutes	– Health questions since last visit – Return & review diary from Visit 1 – **Blood draw (20 mL)** – Complete daily health questionnaire – Nasal self-swab training and distribution of material
Contact 1 **(6 months after Day 1)** Time: 5-10 minutes	– Health questions
Contact 2 **(End of 1st RSV season)** Time: 5-10 minutes	– Health questions
Visit 3 **(Before 2nd RSV season)** Time: 30-60 minutes	– Health questions – Physical exam & vital signs – EQ-5D and SF-12 questionnaires
Contact 3 **(End of 2nd RSV season)** Time: 5-10 minutes	– Health questions
Visit 4 **(Before 3rd RSV season)** Time: 30-60minutes	– Health questions – Physical exam & vital signs – EQ-5D and SF-12 questionnaires
Visit 5 **(End of 2nd RSV season)** Time: 15-30 minutes	– Health questions

Activities when you have cold-like symptoms:

From the day of vaccination (Visit 1) until study end, you will be asked to inform the study staff each time you have 2 or more cold-like symptoms. It is very important for the success of the study that you do this for each cold so we can check if your cold was caused by RSV. The study staff will provide you with a handbook and explain to you what symptoms you have to look for.

From the 2nd visit onwards until study end, you will also be regularly contacted by the study staff to check if you have any cold-like symptoms. These contacts may be done by phone call or e-mail:

- every 2 weeks during the RSV seasons,
- every month during the period between 2 RSV seasons.

Each year, the RSV season is from October 1st to April 30th.

Each time you have 2 or more of these cold-like symptoms, the following table describes what activities will happen:

Day	Activities
Day 1 – Start of cold-like symptoms	– Experience 2 or more cold-like symptoms
Day 2 – Phone Call	– Call Study Staff within 24 hours of cold-like symptoms onset – Answer health questions – Perform a self- swab within 2 days of symptom start and return swab to CCfV within 2 days after collection * – Complete daily health questionnaires ** – Schedule in-person visit
Days 3-7 – Visit within 2-6 days after start of cold-like symptoms	– Complete EQ-5D and SF-12 questionnaires – Complete daily health questionnaires ** – Answer health questions – Physical exam & vital signs – Sample from nostril and throat
Day 15 – Follow-up contact 2 weeks after start of cold-like symptoms	– Complete daily health questionnaires ** – Answer health questions
Day 29 – Closure contact 1 month after start of cold-like symptoms	– Answer health questions
Additional follow-up contacts every 2 weeks if needed	– Answer health questions

* Since how to perform the self-swab will be explained at Visit 2, you do not need to do this activity if you get cold-like symptoms before visit 2.

** You will need to complete the daily questionnaires about your health and symptoms until your cold-like illness is resolved or for a maximum of 14 days in a row after your symptoms have started.

If you still have symptoms after 2 weeks, the study staff will contact you again about 2 weeks later to see if your symptoms have settled. In case you have any complications, they will contact you every 2 weeks until your symptoms have resolved or until the end of the study.

During the study, you should also inform the study staff if you saw a medical doctor or were

hospitalized for a cold-like illness. The study staff will collect some information from your medical records, if needed, by contacting the medical doctor who treated you.

Special situations like the COVID-19 pandemic:
Government and health authorities may issue advice and may impose certain restrictions in special situations (like the COVID-19 pandemic). It is important that you follow all official advice.

What changes may be made in a special situation?

1. Some study visits may be replaced by a telephone call, e-mail, or other modes of virtual contacts. Your preferred method of communication will be used.
2. If you have cold-like symptoms, the study visit may be delayed (up to 14 days after the start of your symptoms) to follow local recommendations for suspected or confirmed COVID-19 cases.
3. You may be asked to visit another clinic/hospital.
4. You may be given and/or asked to share diary cards with the study doctor/staff by e-mail and/or by phone.

What are the burdens, harms, and potential harms?
The vaccine used in this study may cause side effects. However, not everyone will have these side effects. Doctors do not know all the side effects that may happen. Everyone taking part in the study will be observed carefully for any side effects.

Side effects that may occur with the RSV vaccine:
Symptoms of a severe allergy (including itchy skin rash, swelling of the face, difficulties in breathing and swallowing, or a sudden drop in blood pressure) have been rarely reported after administration of medications, including vaccines (up to 1 in 1000 people). If allergic reactions occur, they usually start very soon after vaccination. Therefore, it is important that you stay under observation for at least 30 minutes after vaccination, where all medical equipment and personnel are available to treat any allergic reaction that may occur.

The vaccine that will be used in this study has been given to a small number of people of 60 to 80 years of age in a previous study. Based on the results from this study, you must be aware that you might experience the following side effects with the RSV vaccine which may affect at least 1 in 10 people:

- Pain at injection site
- Redness at injection site
- Swelling at injection site

This study vaccine contains a substance called “adjuvant”. This substance may improve the immune response to the vaccine. People who have received vaccines that contain an adjuvant have very rarely (up to 1 in 10 000 people) developed illnesses called “autoimmune diseases”, which can sometimes be serious and lifelong. Autoimmune diseases may develop when immune cells that normally protect you from illness, attack your own organs instead. These illnesses have also developed in people who have not received these vaccines. Since no one knows for sure if vaccines

with adjuvants might cause autoimmune diseases, GSK continues to monitor autoimmune diseases closely.

Side effects from the placebo:
The use of placebo does not usually cause side effects other than the ones known for any vaccination, such as fainting in response to the needle injection.

Potential risks linked to sample collection:
When giving blood, you may feel faint or experience mild pain, bruising, irritation or redness from the needle.

When taking a swab sample from the upper part of your nose, there is a small chance you may have a nose bleed. A throat swab may cause a short period of gagging because the back of the throat is a sensitive area, but it should not be painful.

What are the possible benefits?
There may or may not be a direct medical benefit to you if you take part in this study.

It is not yet known if the vaccine will protect you from infection with RSV.

You may be assigned to the group that gets the placebo injection. This injection will not protect from infection with RSV.

This study may help us learn more about RSV disease and the effects of the investigational RSV vaccine. By your committed and active participation, you may help make new vaccine(s) to protect people against RSV.

What alternatives to participation do I have?
You do not need to take part in this study. There is currently no specific treatment or vaccine available against RSV in adults.

The standard treatment for adults with RSV infection is usually to treat the symptoms (e.g., oxygen or antipyretics such as acetaminophen or ibuprofen). There are no approved commercially available treatments for persons infected with RSV.

Can I withdraw from the study?
You may withdraw your consent to take part in this research study at any time without penalty or loss of benefits. You do not need to give a reason if you choose to leave. Your choice will not change the quality of care you will receive outside of this study.

If you choose to leave this study, all the data and samples collected while you were in the study will remain as part of the study. These data and samples will be used as described in this form.

The study doctor may find out information about your health after you have left the study. For example, results from your participation (e.g. swab results) might become available after you

withdraw. If this information relates to the safety of the vaccine you received during the study, the study doctor will send it to GSK.

Can you be asked to leave the study?

You may be asked to leave the study if:

- Test results show that this study is not right for you.
- You do not follow the study instructions.
- The study doctor thinks it is best for you to leave, for example if you develop specific health problems.
- The entire study needs to be stopped for everyone.

If this happens, the study doctor will explain the reason to you and ensure proper follow-up.

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. As reimbursement for out-of-pocket expenses such as travel costs to and from study visits, you will receive $50.00 per visit for each visit and a parking pass at the end of each visit if required (if you park in the IWK parking garage).

If you require an unscheduled visit due to illness you will receive $50.00 per visit.

Payment can be made by gift card or cheque through Dalhousie University. If you chose a cheque, you will be asked to sign a form to receive payment by cheque and payment will be made approximately 6 weeks after signing the form.

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.

Are there any conflicts of interest?

There are no known conflicts of interest on the part of researchers and/or CCfV. Funding from GlaxoSmithKline (GSK) 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 will not receive any of the financial benefits.

GSK will own the study results. GSK plans to use the results, and may get patents, or sell the vaccine in the future, or make profits in other ways. You will not be paid any part of this.

How will I be informed of study results?

When the research study is finished at all the study sites, the study data will be looked at and the research study results will be shared with the study doctor. You may ask the study doctor for the results and have them explained to you. The study doctor can share a summary of the research study results in simple language with you and you will be informed which vaccine you received.

This may take many months after the study has been completed. The results will be sent 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 contact information, so we are able to contact you with study results.

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. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive. 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 participant. 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.

What will happen to your samples?

Your samples will be given a unique code number. The code number will not identify you directly and will not have your personal information (data).

Your samples may be sent to GSK laboratories, other laboratories working on behalf of GSK or institutions working with GSK. These institutions and/or laboratories may be outside the country where you live.

Your blood samples will be tested to look at how your body reacts to the study vaccine. For example, your body defenses (called antibodies) to RSV will be measured in your blood. Samples from your nostrils and throat will be tested for RSV and may be tested for other respiratory viruses.

Your samples will also be used to perform additional tests, during and after the study to:

- Ensure the quality of the tests used for the study vaccine or disease(s) is maintained over time,
- Develop and improve tests used for the study vaccine or disease(s).

These tests will never include genetic testing. Genetic testing means tests to look at your family traits (the things passed down in your family).

Your samples will be kept for a maximum of 20 years from the end of the entire study.

What kind of personal and medical information will be obtained during the study?

The study doctor and other study staff will collect data that can identify you. This may include your name, address, phone number, e-mail address and past treatment history. All your data collected for this study will be stored in the study medical records at the study site.

During this study, you will be assigned a unique code number. Your data will be collected and shared only in relation to this code number. Data that directly identifies you will not leave the study site or be sent to GSK.

The data collected about you will be held by CCfV and GSK and/or third parties working on behalf of GSK and/or institutions working with GSK. GSK will protect all data collected about you and will only share it as described in this consent form.

The coded data may be:

- Shared by GSK with health agencies.
- Used to test and improve computer software used by GSK.
- Combined with results from other studies to learn more about the vaccine and related diseases.

At times, GSK may need to anonymize your data. This means your code number can no longer be linked to you. GSK, other scientists and organizations use anonymized data to learn about diseases and medicines. It may be used for this study or other purposes, including further research, once the study is complete.

If you do not agree with the use of your data as described in this form, you cannot join this study.

Why will your data be collected?

Various data related to your participation in this study will be collected. GSK will use this data to address the purpose of the study, as well as for scientific and medical publications. Your data will be coded and handled as described earlier in this form.

Who will be able to see your data?

Your data may be shared with:

- GSK, third parties working on behalf of GSK or institutions working with GSK (including IRBs and IECs that approve and check or monitor studies). This is done to make sure that the study is being run properly.
- The researchers at this study site.
- Regulatory agencies, such as Health Canada, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) or others, who review and approve new vaccines or medicines. These agencies will be granted direct access to your data. This is so that they can verify clinical study procedures and/or data.

Although the study results may be published in medical journals, on the internet and discussed in meetings, data that identifies you will not appear in any publication or in any meetings.

What happens if your data is transferred?

Your coded data may be transferred to trusted persons in other countries. Data protection and privacy laws may not be as strong in these countries as in Canada. However, when data is transferred, GSK makes sure that appropriate and suitable safeguards are used.

More information about the safeguards used is found at:

- https://ec.europa.eu (use the site search function to search for "model contracts for the transfer of personal data"); and
- http://se.gsk.com/media/248019/binding-corporate-rules-policy.pdf (GSK's Binding corporate rules)

What are your rights to access your data?

At any time, you may ask the study doctor to look at your data. In certain circumstances, you may request:

- To learn more about what is done with your data.
- A copy of your data.
- To correct and/or delete your data.
- To transfer your data to a third party (such as your personal doctor), in a format suitable for re-use.

You may also:

- Object to what is done to your data.
- Complain to your local data protection authority, if your privacy rights are violated.
- Claim compensation for damages caused due to unlawful use of your data, through the courts.

In order to protect the integrity of the study results, treatment given to you or study test results will not be disclosed until the completion of the study, except in case of medical emergency.

How long will your data be used?

Your data will be used only for as long as it is needed for the study and further research, with your consent. It may be kept for longer, where required by law. GSK must keep the coded data from research studies for a minimum of 30 years.

Who will collect and process your data?

A data controller collects and processes data. It determines why and how it is processed. GlaxoSmithKline Biologicals SA is the data controller for this study, acting on behalf of the Canadian affiliate GlaxoSmithKline Inc.

Where else can you find information about this study?

There will be a description of this study on the GSK Study Register http://www.gsk-clinicalstudyregister.com and/or other clinical trial registries. It may also appear in clinical trial registries in countries where the study is conducted.
A description of this study will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include data that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

In Canada, information regarding this study will be posted on the Health Canada Clinical Trial Database website https://health-products.canada.ca/ctdb-bdec/index-eng.jsp. This database does not contain comprehensive information about the study or any information that can identify you.

What is meant by further research?

Further research means GSK or others, such as universities or other companies, may do additional research on your samples and coded data other than just what is done for this study.

If you agree, your samples that are left over after the end of the study and your coded data may be used for:

- Further research related to the study vaccine and/or disease(s) of the airways and lungs. This means additional studies conducted to understand the study vaccine and/or disease(s) of the airways and lungs better.
- Further research NOT related to the study vaccine and/or disease(s) of the airways and lungs. This means additional studies conducted to understand other vaccines(s) and/or diseases or for the development of new treatments or research methods. In this case, this research will always be approved by an IRB and/or IEC. This research will never include genetic testing.

The results of these further research studies will not be shared with you. Even if you disagree to the optional use of samples and coded data, you can still join the study. You will be asked to indicate your choice on the signature page.

Communication of research study information

The study doctor will tell you if a new vaccine or treatment for RSV becomes available in your country during this study. You can then decide if you wish to leave the study to receive this new vaccine or treatment or to continue in this study. Any other new information that might change your choice to stay in the study will be shared and discussed with you as soon as possible.

After the study has ended, the study results will be shared with the study doctor. You may ask the study doctor for the results and he/she will explain the results to you.

GSK will develop an easy to read summary of the study results. This result summary will be made available on https://www.trialsummaries.com. You may sign up now for an email notification when the summary becomes available.

Contact for future CCfV studies:

You will be asked at the end of the study if we can contact you for future studies 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. 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 contact the Study Coordinator, Angi Perreault at 902-470-3741 or angela.perreault@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.

For questions or requests regarding what is done to your data, please first contact the study doctor or site's data privacy officer. You can also contact the GSK's Data Privacy Officer at EU.DPO@gsk.com.

Study Title: A Phase 3, randomized, placebo-controlled, observer-blind, multi-country study to demonstrate the efficacy of a single dose of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above.

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 be contacted and given information about future studies. Circle: **Yes or No: Initial____**

I consent to GSK, study staff, and others accessing and using my samples and coded data for further research **related** to this study vaccine and/or disease(s), once the study is complete.
Circle: **Yes or No: Initial____**

I agree that my samples and coded data can be used for future research **not related** to this study vaccine and/or disease(s), once the study is complete
Circle: **Yes or No: Initial____**

***You do not need to answer Yes to all the questions and can still participant in the study.**

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: _____