

INFORMATION & CONSENT FORM

RESEARCH TITLE: A Phase 3, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate The Efficacy And Safety of a Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in Infants Born to Women Vaccinated During Pregnancy

SHORT TITLE: Study to Assess Safety and Effectiveness of an Investigational Respiratory Syncytial Virus (RSV) Vaccine in Healthy Pregnant Women and their Baby.

PROTOCOL NUMBER: C3671008

RESEARCHERS:

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Introduction

Thank you for taking the time to consider joining this study. This consent document can help you make your decision by explaining what you can expect to happen during this study, also known as a clinical trial or a research study.

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

We encourage you to have conversations with your family, caregivers, doctors, and study team about taking part in this study and whether it is right for you. The study team will work with you to answer any questions that you may have about the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

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

Why are the researchers doing the study?

The purpose of this study is to find out if Pfizer's investigational RSVpreF vaccine prevents the development of Respiratory Syncytial Virus (RSV) illness in your baby. A new investigational vaccine is one that is not approved for use in Canada.

RSV is a virus that can cause respiratory illness in people of all ages. Babies less than 6 months old are the most likely to get serious RSV illness, like difficulty breathing or pneumonia (lung infections) that leads to hospitalization. Currently, there is no specific treatment for RSV disease or any vaccine to protect against RSV infection.

Vaccines stimulate the immune system to help make antibodies that help to fight against diseases; this is called an immune response. During pregnancy, the antibodies produced after vaccination by the mom should crossover to their baby through the placenta, and help the baby also fight against diseases.

RSVpreF will be compared with a placebo to find out if it's better at preventing RSV disease. The placebo is like RSVpreF but does not contain any active ingredients. Researchers will compare the results of taking the placebo to the results of being given RSVpreF to see if there are any differences. This study will also assess any side effects after RSVpreF is injected, will measure your immune response to the vaccine, and how well the antibodies you make can help protect your baby from developing an RSV illness.

Because this is a research study, RSVpreF will be given to you only during this research study and not after the research study is over.

How will the researchers do the study?

Approximately 6900 healthy pregnant women will be enrolled in the study at sites in 17 countries including Canada. Approximately up to 20 will take part at the IWK Health Centre in Halifax.

If you participate in the study, the study vaccine you receive will be assigned by chance (like flipping a coin). You will receive one of the 2 possible treatments (RSVpreF or placebo), with a 50% chance of receiving the study vaccine (RSVpreF) or a 50% chance of receiving the placebo. The "placebo" in this study is an injection that is like RSVpreF but does not contain any active ingredients.

This is a double-blinded study. A double-blinded study means that neither you, nor the study doctors, nor the study team will know which investigational product you are receiving. This is done to make sure the results of the study cannot be unfairly influenced by anyone. In case of urgent need, the study team can learn quickly which investigational product you are receiving.

You are being asked to take part in this study because you are a healthy pregnant woman and you are between 18 and 49 years of age, would be between 24 and 36 weeks gestational age on the day of the planned study vaccine, and are expecting a healthy baby. Gestational age is a medical term used to describe how far along your pregnancy is.

This study will explore whether giving the study vaccine, Respiratory Syncytial Virus vaccine (RSVpreF for short) may help protect babies against RSV infection. The safety of RSVpreF will also be assessed. This study is different from your and your baby's regular medical care. The purpose of regular medical care is to improve or otherwise manage your and your baby's health, but the purpose of research is to gather information to advance science and medicine and does not replace your or your baby's regular medical care.

You will be in this study for up to 6 months after your baby is born, which may be up to 10 months in total, depending on your gestational age at the time of vaccination. The total duration will depend on when your baby is born. You will need to visit the study site for approximately 4 planned visits during the study. Your baby will be in the study for up to approximately 24 months. You (or your baby's caregiver) will need to take your baby to visit the study site about 5 times.

You will be required to visit the study staff approximately 4 times to undergo study procedures and to provide information about your health. Once your baby has been born, there will be a routine newborn examination and study assessments, and they will also attend up to 5 study visits to undergo study assessments and procedures. You will also be required to contact the study doctor whenever you or your baby has a medical visit or visits a healthcare provider (e.g. hospital, clinic, emergency room, or home visit) due to a respiratory tract illness, or just to inform them about you and your baby's health.

What will I be asked to do?

Before any study procedures begin you will be asked to read, understand, and sign this consent document. The consent document you sign now will be for your agreement that both you and your baby will take part in the study. **In order to participate in this study, you must agree that both you and your baby will follow the visit schedule and procedures.**

After signing this consent document, you will have a screening assessment visit to find out if you and your unborn baby meet all of the requirements to take part in this study. If you (or your unborn baby) do not meet the requirements, you will not be able to take part in the study and the study doctor will explain why this is the case.

You and your baby will have the following procedures or assessments in this study:

Confirm that you are eligible to participate in this study: If you are eligible, your study doctor or nurse will tell you when you need to come to the study site. At every study visit the

study doctor or the study staff will check again whether you and your baby can continue to be eligible for participation.

Health Status: At your screening and randomization visit (Visit 1): You will be asked questions about your health (past and current, including details about your pregnancy) and about certain personal information (i.e., date of birth, race, and ethnicity). The study staff will also examine you and measure your vital signs (blood pressure, heart rate, and oral temp). They will perform an external exam and check your pregnancy (including checking fetal heart tones and movement). We will need to obtain a copy of your ultrasound.

- At each study visit, the study doctor will ask about medications or treatments that you may have received since the last time you were seen.
- At each study visit, your study doctor or the study staff will ask whether you have experienced a respiratory tract illness which required a medical visit. Information relating to this illness visit will be captured by the study staff.

At delivery, or within 7 days of delivery: Your baby's birth information will be collected including length, weight, head circumference (measurement around his/her head), as well as temperature, heart rate, and respiratory rate, blood oxygen saturation, newborn physical exam details and demographic information (i.e., gender, date of birth, race, and ethnicity). A blood sample will be collected from your baby if cord blood is unattainable at delivery.

Your baby will be examined at each visit done at the study clinic or at home (1, 6, 12, 18 and 24-month visits), with the following measurements taken at each visit:

- Length, weight, head circumference (measurement around his/her head), vital signs such as temperature, heart rate, blood oxygen saturation and respiratory rate (at 1-month visit only).
- From the time your baby is born through the 24-month visit, the study doctor or study team will ask about your baby's health and any medications, treatments or vaccinations that your baby may have received since the last visit.

Please note: breast milk donation to other infants while participating in this study is not allowed.

Blood Samples: A blood sample of 15 mL (approximately 3 teaspoons) will be collected from a vein in your arm using a needle. The blood will be taken to determine if your body has produced substances (antibodies) in response to the study vaccine. This sample will be taken: before you are given the study vaccine (baseline) on Day 1 (Visit 1), and during labor/at delivery (Visit 3).

The study staff may need to collect blood samples to determine your eligibility for this study if they have not been previously performed in the current pregnancy. We will need to obtain copies of these results. Negative Hepatitis B, syphilis, and human immunodeficiency virus (HIV) blood test results are required for you to take part in this study. If you are not eligible to continue in the study due to your blood test results, the study team will call you and inform you that you will not be able to continue in the study and the study doctor will explain why.

Cord blood sample: A blood sample will be taken and used to measure antibodies transferred from you to your baby as a result of the study vaccination. A cord blood sample, approximately 10 mL (approximately 2 teaspoons) of blood will be collected from the umbilical cord, which goes from what becomes your baby's belly button to your placenta. This happens after the umbilical cord has been clamped and cut in the delivery room. If cord blood was not taken, a blood sample of up to 5 mL (approximately 1 teaspoon [depending on your baby's weight]) will be taken either from a heel prick or from a vein through a needle up to 7 days after birth.

Study Vaccination: If you qualify for the study you will be given a study injection of RSVpreF or placebo into the muscle of your upper arm at Visit 1. You will need to stay in the clinic for at least 30 minutes for the study doctor or nurse to check on you to make sure that you are feeling well after vaccination.

Electronic Diary: On the day of your study vaccination, the study staff will show you how to fill in an electronic diary (called an "e-diary", for short). You will be given a digital thermometer and a measuring device (caliper) to take home. The study staff will show you how to use the digital thermometer and measuring device.

- The **e-diary** is a device that looks like a smartphone and will record your responses to questions asked of you. If you prefer, instead of receiving an e-diary, you can download a mobile application (app) to your smartphone (Android or iPhone). The study staff will show you how to answer the diary questions. The e-diary will ask questions about how you have felt over the last 7 days **before** receiving the study vaccine and will ask questions about any potential side effects that you may have after receiving the study vaccine daily for 7 days.
- You will use the digital **thermometer** to measure your temperature under your tongue. You will need to record the temperature in your e-diary in Celsius (°C).
- You will need to use the **measuring device** to measure the size of any redness or swelling on your arm where the study vaccine was given. You will need to record the measurement in your e-diary.

You will need to complete the diary in the evening after receiving the vaccination in the arm and then for 6 more days in the evening. This is a total of 7 days. You will be reminded to bring the e-diary device, or your own smartphone with the study app, with you to the 1-Month visit (Visit 2). If you have any ongoing symptoms after you have completed your e-diary on Day 7, you must tell the study staff when these symptoms end and provide details of any fever/pain medication taken.

Additional Follow-up Procedures and Site Contact Activities

Important: The purpose of this research study is to gather information to advance science and medicine and does not replace your or your baby's regular medical care.

You must call the study nurse or doctor, if you experience a large area of redness, discoloration, or swelling at the study injection site (21 units or bigger on the measuring device), a temperature more than or equal to 39.0°C (102.2°F), or severe injection site pain, severe nausea/vomiting, severe diarrhea, severe headache, severe tiredness, severe muscle pain and/or severe joint pain. If you visit the emergency room or are hospitalized, you should contact the study site immediately.

You may be asked to return to the study site for extra visits if you have a severe reaction after your study vaccination.

The study doctor or nurse may schedule extra assessment visits. At this extra visit:

- You will have your vital signs (temperature, heart rate, and blood pressure) measured.
- The size of any redness or swelling around your study vaccination site will be measured.
- You will be asked about your health.
- The doctor or nurse may also examine you and ask you questions about your reported symptoms.

Baby Monitoring for Respiratory Tract Illness: You will be asked to contact the study site as soon as possible each time your baby has a medical/healthcare provider visit due to signs of a respiratory tract illness. This contact may be via your e-diary or corresponding study communication tool, a text, email, phone call or face to face visit, and will be:

- Weekly once you have had your baby, until approximately 6 months after delivery of your baby.
- Monthly, from month 6 until your baby is 24 months old (2 year old).

You will be asked about the following respiratory symptoms that resulted in your visit to the healthcare provider:

- Discharge from the nose for 24 hours or more,
- Difficulty breathing, labored breathing, or rapid breathing for any duration,
- Cough,
- Inability to feed for any duration due to respiratory tract illness,
- Reduced or paused breathing,
- Any other respiratory symptom you are concerned about.

If your baby experiences a respiratory tract illness that results in a visit to a healthcare provider, please notify the study doctor or study site staff as soon as possible to schedule an assessment visit. Your baby will have the following procedures or assessments:

Health Status: Your baby's body weight, temperature, heart rate, respiratory rate, and blood oxygen saturation will be obtained.

Medication and/or treatments: The study staff will ask questions about your baby's health, including medications or vaccinations given since last being seen by the study site, breastfeeding information (if applicable) and if your baby is going to daycare.

Background information about your family circumstances: The study doctor or study staff will ask questions about number of missed days of work for your baby's caregiver (e.g. you, your partner, or other caregiver due to your baby's respiratory illness).

Nasal swab samples: A nasal swab sample will be collected from your baby's nose during this assessment visit. The results of this sample are used to detect respiratory viruses or infection. This type of sample will be collected only at the sick visits where a respiratory illness has been confirmed. You will not be able to have the results of the nasal swab test, since it is not done

right away. The study staff may contact you after an assessment visit to follow-up on the well-being of your baby.

Nasal swab sample during a disease outbreak or a natural disaster (if applicable):

- You/the infant’s caregiver/your healthcare provider may be required to collect the nasal swab sample from your baby’s nose, using the nasal swab kit provided by your study site. **As this is a very important part of the study, the study team will give you detailed instructions on how to do this.** You will then need to contact a courier to pick up the sample to take it to your study site for testing.
- The study staff will provide training, educational material and a nasal swab collection kit for you/the infant’s caregiver/your healthcare provider to help collect the nasal swab sample after a confirmed respiratory illness. Collection of the nasal swab sample should occur during or as soon after the medical visit as possible and within 10 days of the confirmed respiratory illness visit. You will not be able to have the results of the nasal swab test, since it is not done right away.
- The nasal swab collection kit includes the nasal swab, nasal swab transport medium tube to store the nasal swab once the sample is collected, instruction card, and a sample requisition card. The instructions detail how to ship the nasal swab sample to your study site.

You also will be given a card with important emergency contact information, including a 24-hour number. Show this card to any doctor, nurse or other health care provider if you seek emergency care while you are taking part in this study. This card includes information about the study that will help them treat you. Also, please tell the study staff about any visits that you/your baby has at another department or hospital.

What happens for you and your baby during each study visit is detailed in the table below:

Visit Day	Maternal (Mother) Study Details	
Visit 1 - Maternal (24-36 weeks gestation) Time: 60-75 minutes	<ul style="list-style-type: none"> - Informed consent process - Review study eligibility & health status - Review your previous ultrasound and bloodwork - Physical exam & vital signs - Blood (15 mL) sample - <u>Vaccination</u> - 30 minute wait - Receive electronic diary 	
*Visit 2 - Maternal (28-42 days after vaccination) Time: 15-30 minutes	<ul style="list-style-type: none"> - Review electronic diary - Review health status since last visit - Medication review 	
	Maternal Study Details	Baby Study Details

Visit 3 - Maternal Visit 1 - Baby (Delivery Day) Time: 15-30 minutes	<ul style="list-style-type: none"> - Review health status since the last visit - Blood Sample (15 mL) - Collect labour & delivery information - **Review nasal swab collection kit use 	<ul style="list-style-type: none"> - Cord blood collection - (If unable to obtain cord blood, a blood sample - maximum 5 mL (about 1 teaspoon) will be collected) - Collect birth & physical assessment information
Visit 2 - Baby (28 days old) Time: 30-45 minutes **Note: this Visit may be conducted as a home visit.	<ul style="list-style-type: none"> - **Review nasal swab collection kit use 	<ul style="list-style-type: none"> - Review health status since the last visit - Physical exam & vital signs
Visit 4 - Maternal Visit 3 - Baby (6 months old) Time: 30-45 minutes **Note: this Visit could be a home visit or phone contact	<ul style="list-style-type: none"> - Review health status since the last visit - **Review nasal swab collection kit use 	<ul style="list-style-type: none"> - Review health status since the last visit - Physical exam & vital signs
Baby Study Details		
*Visit 4 - Baby (12 months old) Time: 15-30 minutes	<ul style="list-style-type: none"> - Review health status since the last visit - Physical exam & vital signs 	
*Visit 5 - Baby (18 months old) Time: 15-30 minutes	<ul style="list-style-type: none"> - Review health status since the last visit - Physical exam & vital signs 	
*Visit 6 - Baby (24 months old) Time: 15-30 minutes	<ul style="list-style-type: none"> - Review health status since the last visit - Physical exam & vital signs 	
Weekly Contacts - Baby: Birth to 6 months old Time: 5-10 minutes/contact	<ul style="list-style-type: none"> - Review health status since the last contact. - Reminder to contact study staff if there are RTI symptoms that require a <u>doctor</u> visit. 	
Monthly Contacts - Baby: 6 to 24 months old Time: 5-10 minutes/contact	<ul style="list-style-type: none"> - Review health status since the last contact. - Reminder to contact study staff if there are RTI symptoms that require a <u>hospital</u> visit. 	
Respiratory Tract Infection (RTI) Visit		
Baby: Birth to 6 months (if your child develops RTI)	<ul style="list-style-type: none"> - Questions about your baby's health - Physical examination & vital signs, body weight 	

symptoms that require a <u>doctor</u> visit) Baby: 6 to 24 months (if your child develops RTI symptoms that are severe or require a <u>hospital</u> visit) Time: 15-30 minutes	<ul style="list-style-type: none"> - Nasal swab (mid-turbinate swab is inserted into one nostril until resistance is met and the stopper touches the tip of the nose***) - Record any medications and information about your baby's visit to the healthcare provider including any assessments performed
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*Visit can also be done as a phone call.

**If medically necessary (e.g., during a disease outbreak or natural disaster), study visits, excluding in-person study assessments (e.g., physical exam and/vital sign measurements) may be conducted by telephone.

***If medically necessary (eg during a disease outbreak or natural disaster), the nasal swab sample can be collected by you/your infant's caregiver/ your healthcare provider as soon as possible, during or after your infant's visit to a healthcare provider due to a respiratory illness (Note: maximum window of 10 days).

Are there any special instructions to follow for this study?

It is important that you:

- Tell the study doctor if you previously took part in this study or a similar study, have been in any other study in the past 28 days, or are currently involved in any other study.
- Do not take part in any other study without approval from the study doctor. Tell the study doctor immediately if you/your baby are taking part, or want to take part, in other studies while you are taking part in this study. Participating in more than one study at the same time could put your or your baby's safety at risk.
- Follow the instructions you are given by the study doctor and study team. If you do not follow the instructions, your/your baby's visit may have to be rescheduled and/or you/your baby may not be allowed to continue to participate in this study.
- Tell other doctors, nurses, and health care providers about your/your baby's participation in this study by showing the information card provided to you by the study team.
- Tell the study doctor or the study staff about all prescription and non-prescription medications, supplements, or vaccines (e.g., flu shot) before you/your baby take them.
- Notify the study team if you/your baby move and provide the new contact information.
- Tell the study team if you are planning on travelling while you are in the study, especially if this involves going overseas or to another time zone.
- Tell the study doctor or the study staff if your e-diary device, thermometer or measuring device is not working properly.
- Call the study doctor or study staff if you have a large reaction (redness/swelling) at the study vaccination site, or any severe reaction.
- Call the study doctor or study staff as soon as possible, if your baby develops any respiratory symptoms that may have triggered a sick visit to a healthcare provider.

- Tell the study doctor or the study staff if you/your baby are not able to comply with the study requirements.
- Tell the study doctor or the study staff if you require a replacement nasal swab kit.
- Tell the study doctor or the study staff about any changes in your/your baby's health.

What are the burdens, harms, and potential harms?

All research has some risk, which may include things that could make you or your baby feel unwell or uncomfortable, or that could harm you or your baby. You or your baby might experience these risks or discomforts while taking part in this study.

It is important that you tell the study team if you or your baby are feeling any of these things during the study. The study team will monitor you and your baby for risks or discomforts during the study. However, the study team does not know all the effects that the study vaccine, or you/your baby's participation in this study, may have on you or your baby.

These effects might be mild or serious. In some cases, these effects might be long-lasting or permanent, and might even be life-threatening. The study team may determine that you or your baby need additional procedures or medicines to help manage side effects. The study doctor also may decide to remove you or your baby from the study.

If you and your baby take part in this study, the most likely risks or discomforts to happen to you and your baby are discussed below.

It is important that you report to the study team all symptoms and side effects as soon as they occur.

Study vaccine risks (RSV)

Pfizer's investigational RSV vaccine is being assessed in four ongoing studies. Three studies are being conducted in healthy adults 18 through 85 years of age and one study is being conducted in healthy pregnant women 18 through 49 years of age. More than 2000 healthy adults 18 through 85 years of age have been vaccinated with RSVpreF and are being followed for 12 months after vaccination.

The known side effects of this RSVpreF are similar to those commonly observed with other vaccines and include:

- Injection site redness
- Injection site swelling
- Injection site pain or tenderness
- Fever
- Tiredness
- Muscle pain
- Headache

In the first in human study, in the younger group 18-49 years old, the frequency of any local reactions (redness, swelling and pain at the injection site) and systemic reactions (headache, tiredness, muscle pain, joint pain, nausea, vomiting, diarrhea and fever) was very common (more

than 10%) in all doses and formulations, including the placebo. The maximum severity of reported local reactions and maximum severity of reported systemic events were predominantly mild or moderate across all doses and formulations.

There may be other risks that currently are unknown because RSVpreF is investigational.

As with any vaccine given by injection, very rarely people may have an allergic reaction. The allergic reaction could be minor (rashes) or more severe including:

- Swelling of the face or lips (edema)
- Wheezing (bronchospasm)
- Difficulty in breathing (dyspnea)

If you have symptoms of an allergic reaction you should seek medical attention immediately. A severe allergic reaction (anaphylactic shock) may occur and could be life threatening.

It is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study vaccine.

Placebo

Some women taking part in this study will receive placebo. The placebo in this study is a dummy vaccination that may look like RSVpreF but does not contain any active ingredients. Reactions that have been seen at the injection site include pain, bruising, swelling and redness.

The risks associated with the study vaccine (RSVpreF or placebo) may be experienced by you, but not your baby, since your baby will not receive the study vaccine or placebo directly. To date, toxicity studies in animals and clinical trials in humans of this vaccine have not identified any harms to women of childbearing age or pregnant women or their fetus/baby. Maternal vaccines given routinely in public health programs (influenza, Tdap) result in increased maternal antibody which is actively transported across the placenta to the baby. All adverse effects that are known at this time about the study vaccine are described in this form.

Risks from Study Procedures

Risks and possible discomforts you or your baby might have from the study procedures include:

Blood samples

The risks and possible discomforts involved in taking blood include pain from inserting the needle, or less often, swelling, bruising, or infection around the vein where the blood is collected. You may feel dizzy or may faint. If you have a previous history of feeling dizzy or fainting during blood sample collection, you should talk to the study doctor.

Your baby may experience discomfort and cry. Anesthetic cream to numb the pain may be used. We use other methods to decrease pain in babies such as sucrose water and distraction. These samples will be taken by experienced pediatric staff.

Nasal Samples

The risks and possible discomforts involved in taking nasal swabs from your baby may include pain or general discomfort. Sometimes it may cause the nose to bleed.

Other Risks

There may be other risks that currently are unknown because RSVpreF is still investigational.

What are the potential benefits?

This study is for research purposes only. There may not be a direct benefit to you or your baby from taking part. However, the information learned from the study may help other people in the future.

What alternatives to participation do I have?

You and your baby do not have to participate in this study. There currently is no approved vaccine for adults or babies to protect them against RSV and there is no effective anti-viral medication to treat RSV infections. Treatments against RSV disease consist of supportive care (such as oxygen) and may help with the disease symptoms but do not work on the virus that causes the disease. Your/your baby's routine medical care (including that at the IWK Health Centre) will not be affected if you decide to not take part.

There is a synthetic (artificial) antibody to prevent RSV which is given to high-risk babies only. 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?

You may withdraw your consent for you and your baby to take part in this research study at any time without penalty or loss of benefits. Your routine medical care at the IWK Health Centre will not be affected. Tell the study doctor if you are thinking about stopping or decide to stop so that study participation may end in the safest way.

While you are participating, the study team will tell you in right away if new information is learned during the course of the study that could change your mind about continuing in this study. If you decide to withdraw yourself or your baby from the study, you may be asked to continue to participate in collection of safety information.

Sometimes the study doctor or the Sponsor may decide to take you/your baby out of the study (even if you do not agree) if:

- You are unable or unwilling to follow the instructions of the study doctor or study team for either yourself or for your baby;
- The study doctor decides that the study is not in your best interest to continue in the study or that you/your baby are no longer eligible to participate; or
- The study is stopped by the Sponsor, the Research Ethics Board (REB), or a government or regulatory agency.

If you/your baby stop taking part in the study and you do not tell the study team, your contact information may be used by the study team to contact you and check whether you/your baby wish to continue in the study.

If you/your baby stop taking part in the study but do not withdraw your consent, your/your baby's personal information will continue to be used in accordance with this applicable law. No new information or samples will be collected about you/your baby or from you/your baby by the study team, unless you have agreed to provide them.

If you decide to withdraw your consent:

- You/your baby will no longer be able to participate in the study;
- No new information or samples will be collected about you/your baby or from you/your baby by the study team;
- The study team may still need to report any safety event that you/your baby may have experienced due to your/your baby's participation in the study to the Sponsor;
- Your/your baby's personal information, including Coded Information, that has already been collected up to the time of your/your baby's withdrawal will be kept and used by the Sponsor to guarantee the integrity of the study, to determine the safety effects of the vaccine, to satisfy legal or regulatory requirements, and/or for any other purposes permitted under applicable data protection and privacy laws;
- Your/your baby's personal information (including Coded Information) will not be used for further scientific research. However, if your/your baby's personal information has been anonymized so that the information does not identify you/your baby personally, that information may continue to be used for further scientific research, as permitted by applicable law; and
- Biological samples that have been collected but not analyzed will no longer be used, unless permitted or required by applicable law.

You have the additional right to request that any remaining samples that have been collected from you/your baby as part of the study be destroyed. You may exercise this right by communicating to the study team your wish to have the samples destroyed. The study team will then send your coded request to the Sponsor. In some countries, local laws or regulations may require that your/your baby's samples be destroyed or de-identified if you/your baby withdraw from the study, regardless of whether you specifically make such a request.

However, we cannot guarantee the destruction of samples because the sample may no longer be traceable to you/your baby, they may have been used up, or they may have been released to a third party. In those cases, it would not be possible to remove and destroy your/your baby's biological samples and any related data.

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 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).

You will receive \$500.00 in total (if you and your baby complete all the scheduled study visits). This will be paid out after the Baby Visit 2 (\$250.00), Baby Visit 5/Maternal Visit 4 (\$100.00) and Baby Visit 4 (\$.50.00), Baby Visit 5 (\$50.00) and Baby Visit 6 (\$50.00).

You will receive \$50.00 per visit for any unscheduled illness visits that are required if your baby develop RTI symptoms and is seen by a healthcare provider. This will be added to the next scheduled payment.

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

Are there any conflicts of interest?

There are no known conflicts of interest on the part of researchers and/or CCfV. Funding from Pfizer will cover the costs of conducting the study at CCfV, and the study team (study doctor, nurses and assistants) will be compensated for their time and the expenses required 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.

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 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 contact information, so we are able to contact you with study results.

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

The study results, when available, may also be found on www.pfizer.com and <https://www.clinicaltrialsregister.eu/>.

The Sponsor will provide the study doctor with information about the study results when all participants have completed the study. However, your individual study results will not be given to you, your doctor (if different from the study doctor), your family, your employer or any insurance company.

What are my research rights?

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

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

What will happen to your samples?

The samples may be stored in a facility located in a different country from your study site. Each sample will be labeled with a code so that the laboratory workers testing the samples will not know who you are.

Some of the samples may be stored for future testing and may be kept for up to 15 years after the study ends, at which time they will be destroyed. In addition to testing for this study, any samples left over after the study is complete may be used for additional research related to the development of products. No testing of your DNA will be performed.

You may request that your samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of Pfizer and may be shared with other researchers as long as confidentiality is maintained, and no testing of your DNA will be performed. You will not be told of additional tests, nor will you receive results of any of these tests.

How will my privacy be protected?

The information below describes how we will collect, use, and share your and your baby's personal information. It also describes your/your baby's privacy rights.

A. What personal information may we collect about you/your baby during this study?

Your study team and others assisting with your/your baby's study-related care will collect or provide information about you/your baby, some of which is sensitive. This information may include:

- **Information that directly identifies you/your baby** such as your name, address, telephone number, and your and your baby's date of birth, health insurance number/national ID number].
- **Sensitive personal information** such as your/your baby's medical history, data from this study (including study results from tests and procedures), demographics (for example, age

and gender) and other sensitive information that is needed for this study such as HIV/AIDS, substance use disorders, mental health disorders, diagnoses and treatment, race, ethnicity.

- **Data from testing and analysis of biological samples** (such as blood or urine) **and images** (such as X-rays, CT-Scans, and medical photographs). This may also include genetic information.
- **Data captured from electronic devices** if you complete the consent process using the eConsent tablet or if you use a mobile application or other digital tool during the study, such as an e-Diary. This information may include data about your use of the eConsent tablet, application or tool, such as the length of time it takes you to complete the consent process, the number of times you scroll between pages or click on the hyperlinked items, your electronic signature and any other relevant data collected. Mobile applications and other digital tools used in the study may have their own privacy policies. Those policies provide additional information about the data processing activities performed by the digital tools.

B. Who will use my/my baby's personal information, how will they use it, and where will it be stored?

Any personal information collected about you/your baby during this study will be securely stored by the study team at the Canadian Center for Vaccinology at the IWK Health Centre. The study team must keep your/your baby's personal information private.

Your/your baby's personal information will be accessed by:

- Your/your baby's study doctor and other study team members;
- The Sponsor and its representatives (including its affiliated companies);
- People, or organizations providing services for, or collaborating with, the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or rights to the product under study;
- Government or regulatory authorities, such as Health Canada, (including those in other countries); and
- Research Ethics Board(s) (REB) overseeing this study.
- The individuals and groups listed above will use your/your baby's personal information to conduct this study, and to comply with legal or regulatory requirements, including to:
 - determine if you/your baby are eligible for this study;
 - provide you with reimbursement, as allowed by the study, for your time, effort and certain expenses related to your/your baby's participation;
 - verify that the study is conducted correctly and that study data are accurate;
 - answer questions from REBs, or government or regulatory agencies;
 - assess your use of electronic devices in the study, for example, to determine how long it takes you to complete any e-consent module used for the study and your comprehension of the e-consent process;
 - contact you during and after the study (if necessary);
 - follow-up on your/your baby's health status, including using publicly available sources should the study team be unable to contact you using information held on file;
 - protect your/your baby's vital interests (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you/your baby are being treated); and
 - answer your data protection requests (if any).

Information collected during a clinical research study must be retained for 25 years. Accordingly, even if you/your baby withdraw from the study, by law we cannot immediately destroy the information that we obtained from you/your baby.

If you provide someone else's personal information (for example, an emergency contact or details of family medical history) you should make them aware that you have provided the information to us. We will only use such personal information in accordance with this informed consent and applicable law.

C. What happens to my/my baby's personal information that is sent outside the study site?

Before the study team transfers your/your baby's personal information outside the study site, the study site will replace your/your baby's name with a unique code and remove information that directly identifies you/your baby. We call this "**Coded Information.**" The study site will keep the link between the code and your/your baby's personal information confidential, and the Sponsor will not have access to that link. The Sponsor's employees and representatives are required to protect your/your baby's Coded Information and will not attempt to re-identify you/your baby.

Your/your baby's Coded Information will be used by the following:

- The Sponsor and its representatives (including its affiliated companies);
- People and/or organizations providing services to or collaborating with the Sponsor;
- Any organization that obtains all or part of the Sponsor's business or the rights to the product under study;
- Other researchers;
- The REB that approved this study;
- Government or regulatory authorities.

The above parties may use your/your baby's personal information for the following purposes:

- **Conducting the study**, including:
 - Examining your/your baby's response to the study vaccine;
 - Understanding the study and the study results and learning more about RSV; and
 - Assessing the safety and efficacy of the study vaccine.
- **Complying with legal and regulatory duties** such as:
 - Ensuring the study is conducted according to good clinical practice;
 - Making required disclosures to REB(s), or government or regulatory authorities;
 - Seeking approval from government or regulatory authorities to market the study vaccine (it is possible that these government or regulatory authorities may disclose your/your baby's Coded Information to other researchers for the conduct of future scientific research); and
 - Sharing study data with other researchers not affiliated with the Sponsor or study team (including through publication on the internet or other ways. However, information that could directly identify you/your baby will not be made available to other researchers).
- **Publishing summaries of the study results** in medical journals, on the internet or at educational meetings of other researchers. You/your baby will not be directly identified in any publication or report of the study. But, some journal representatives may need

access to your/your baby's Coded Information to verify the study results and ensure the research meets the journal's quality standards. Also, journals may require that genetic and other information from the study that does not directly identify you/your baby be made available to other researchers for further research projects.

- **Improving the quality, design and safety** of this study and other research studies.

The Sponsor will retain your/your baby's Coded Information for the period necessary to fulfil the purposes outlined in the consent document(s), unless a different retention period is required or permitted by law.

D. How are my/my baby's biological samples and images handled?

If biological samples or images of you/your baby are taken during the study, those samples and images will be handled in the same way as your/your baby's Coded Information. All samples will be treated as required by law. Sometimes your/your baby's study site may be unable to remove information that can identify you/your baby from your/your baby's images before sending images to the Sponsor and its representatives.

E. Can my/my baby's personal information be used for other research?

Your/your baby's Coded Information may be used to advance scientific research and public health in other projects that will occur in the future. At this time, we do not know the specific details of these future research projects.

This other research may be conducted (1) in combination with data from **other sources**, (2) for **additional scientific research purposes** beyond objectives of this study, and (3) subject to **specific safeguards**.

- **Other sources:** Coded Information may be combined with data from other sources that are taken from outside typical research settings. These sources may include: coded electronic health records, claims and health care cost and payment data or databases, product and disease registries, data gathered through your phone, tablet, or other devices and mobile applications, social media, pharmacy data, biobanks, or patient engagement programs.
- **Additional scientific research:** Coded Information may be used to understand how to make new medicines, devices, diagnostic products, tools and/or other therapies that treat diseases and to improve future research. It may also be used to inform value, cost-effectiveness and pricing, and to optimize access to medicines.
- **Specific safeguards** will be used to protect your/your baby's Coded Information, which may include:
 - Limiting access to Coded Information to specific individuals who will be obligated to keep this information confidential and will be prohibited from attempting to re-identify your/your baby's Coded Information.
 - Using security measures to avoid data alteration, loss and unauthorized access.
 - Anonymizing the data by removing and/or replacing information from the Coded Information and/or destroying the link to the Coded Information.
 - Assessing data protection systems to identify and mitigate privacy risks, if any, associated to each additional scientific research purpose.
 - When required by applicable law, ensuring that the scientific research has the approval of REBs, or other similar review groups.

How will my/my baby’s personal information be protected when transferred from the study site to the Sponsor?

Your/your baby’s personal information will be treated in compliance with applicable data protection laws.

Some of the people using your/your baby’s personal information, including your/your baby’s Coded Information, may be based in countries other than your country, including the United States. Data privacy laws may be different in these countries. If your/your baby’s personal information is transferred by the Sponsor to other countries, the Sponsor, and people working with the Sponsor, will take steps to maintain the confidentiality of your/your baby’s personal information.

F. What are my/my baby’s data protection rights? Whom may I contact about these rights or any concerns or complaints?

You have the right to access and correct your personal information that is held about you/your baby by the study team. *To ensure the integrity of the study, you will not be able to review some of the data until after the study has been completed.*

If you wish to exercise these rights, or have concerns about how your/your baby’s personal information is being handled, it is best to contact the Canadian Center for Vaccinology and not the Sponsor. Generally, the Sponsor will not know who you/your baby are (by name) because the Sponsor usually holds only your/your baby’s Coded Information, which does not include your/your baby’s name or other information that can easily identify you/your baby. To contact the Canadian Center for Vaccinology or the study team representative, please see the **contact information** on the last page of the consent document.

Contact for future CCfV studies:

You will be asked at the end of the study if we can contact you for future studies for you and your baby 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 call the Research Nurse 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.

Study Title: A Phase 3, Randomized, Double-Blinded, Placebo-Controlled Trial To Evaluate The Efficacy And Safety Of A Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in Infants Born To Women Vaccinated During Pregnancy

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 and let my baby take part in the study. I understand the nature of the study and I understand the potential risks. I understand that my/ my baby’s personal and medical information will be used as described in this form, and that my/my baby’s 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 and let my baby take part 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/my baby’s 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: _____