# Study 214725 Resource Guide

**Dear Parents and Caregivers:**

Look inside to learn more about this clinical study.

# STUDY 214725

Thank you for your interest in joining this clinical study.

We are running this study to support the development of a maternal RSV vaccine. This vaccine might help protect infants against **R**espiratory **s**yncytial **v**irus, also called **RSV,** disease in the future. **RSV** is a contagious cold-like virus that infects the lungs and airways.

## Study Details

- Globally about **378 pregnant women and their babies** will participate in the study.

- The study will take **16 to 17 months** for participating mothers and babies to complete.
  - **For mothers,** the study will take about 10 to 11 months. **For babies**, the study will take about 12 months.

- Researchers are trying to:
  - Find out how well the vaccine can **boost antibodies against RSV** in pregnant women.
  - Make sure the new vaccine is **safe for pregnant adults with HIV infection and/or with pregnancy complications.**

# What are Clinical Studies?

Before a new vaccine or medicine can be marketed and given to many people, it needs to be tested and then approved by national health authorities, like Health Canada.

Several clinical studies, sometimes called clinical trials, are done in many countries to **test potential vaccines or medicines** when given to people.

The overall goal of a clinical study is to gather information to determine whether these new potential vaccines or medicines work well and are safe for people. National health authorities look at the information gathered from these studies and decide if they can approve the new vaccine or medicine.

# What is Informed Consent?

**Informed consent** is a process where the study team gives you information about a clinical study so you can decide if you want to join. **You will be able to ask about anything you do not understand**. You are welcome to bring someone you trust to the conversation.

You will be asked to read an **informed consent form** that describes the study and what taking part in it may mean for you and your baby.

Your decision to take part in a study with your baby is **voluntary**. You can change your decision and leave the study at any time, without giving a reason.

If you decide that you want to join the study after reviewing all information, the study team will ask you to **sign the informed consent form** for yourself and for your baby to participate.

# Taking Part in Study 214725

## What is the Purpose of this Study?

GSK is testing a new vaccine for pregnant women to protect their babies against RSV illness.

- This study is being done to make sure the vaccine is safe and works well.
- When your body is exposed to the vaccine, we expect that your body will make even more antibodies that can fight RSV, which is called “boosting”. We expect that enough antibodies will reach your baby to help them fight RSV in their first months of life.

## What is RSV?

- **R**espiratory **s**yncytial **v**irus, also called **RSV**, is a contagious cold-like virus that infects the lungs and airways.
- A person with a mild RSV illness may have a **cold or sore throat**. A person with severe RSV illness may have **problems breathing.**
- **Almost all children have had RSV by the age of 2 years**. Very young babies are more likely to be very sick with RSV than older children.

### Did you know?

An RSV infection is one of the most common reasons for hospitalization among babies in the first few months of life.

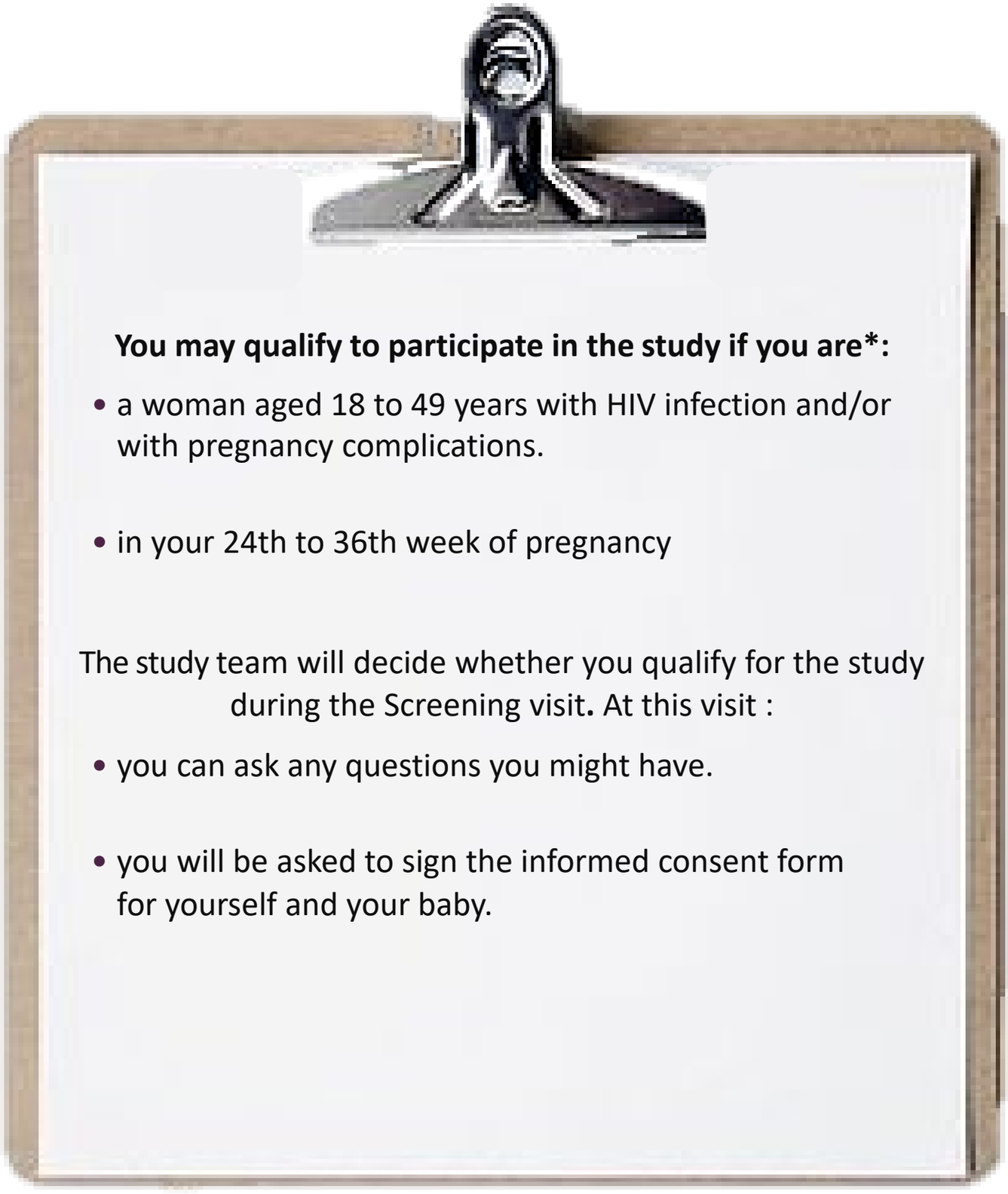
## Which Vaccine Will You Get?

If you take part in this study, you will get either:

- The RSV vaccine or
- The placebo – an injection that is made of sugar and salt water and does not have the ingredient that may protect against RSV.

You will not know which product you get. The study doctor, the person giving the injection and the rest of the site staff will not know either.

# Do I Qualify To Take Part in the Study?



**You may qualify to participate in the study if you are*:**

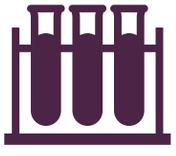
- a woman aged 18 to 49 years with HIV infection and/or with pregnancy complications.
- in your 24th to 36th week of pregnancy

The study team will decide whether you qualify for the study during the Screening visit**.** At this visit :

- you can ask any questions you might have.
- you will be asked to sign the informed consent form for yourself and your baby.

*Additional eligibility criteria apply. Ask the study doctor for more information.

# Key Study Activities

| | | |
|---|---|---|
|  <br>**Medical History**<br>The study team will ask you questions about any previous vaccinations, medicines, or sickness you have had. |  <br>**Medicine and Symptom Review**<br>The study team will ask if there have been any changes to the medicines or vaccines that you or you baby receive*.<br>They will also ask whether you have noticed any changes in your or your baby's health. |  <br>**Physical Exam**<br>The physical exam may include recording height, weight, body temperature, blood pressure, heart rate, breathing rate, and blood oxygen level.<br><br>Mothers also have obstetric exams. |
|  <br>**Blood Draws**<br>Blood samples will be taken from you and your baby at different times throughout the study. These samples help the study team see whether your body is responding to the study vaccine. |  <br>**Vaccination**<br>You will receive the study vaccine or placebo. The study team will ask you to stay at the clinic for a 30-minute observation period after the vaccination. |  <br>**Nose Swabs**<br>If you or your baby has a visit for cold-like symptoms, a soft-tipped swab will be used to collect liquid from you or your baby's nose. This will help us determine if your symptoms are caused by RSV. |

*The study team will tell you which medicines you can and cannot take during the study.

# Your Study Visit Schedule

| Screening | Visit 1 | Visit 2 | Visit 3 | Visit 4 |
|---|---|---|---|---|
| Between 0 to 28 days before Visit 1 | You are 24-36 weeks pregnant | 30 days after Visit 1 | Baby's Birth | 6 weeks after Baby's birth |
| Discuss with the study team, ask any questions and sign the informed consent form<br><br>Medical history<br><br>Physical exam<br><br>Blood draw / Urine test (if not already available) | Receive the study vaccine or placebo<br><br>Blood draw<br><br>Physical exam<br><br>Medicine/ symptom review | Blood draw<br><br>Physical exam<br><br>Medicine/ symptom review | Cord blood sample<br><br>Blood draw<br><br>Physical exam<br><br>Give informed consent for your baby or confirm consent for you<br><br>Medicine/ symptom review | Physical exam<br><br>Medicine/ symptom review |
| | | | **Baby Visit 1** | **Baby Visit 2** |

The study team will **contact** you about **once a month** until you give birth and then at 6 months after birth to **check on the health of you and your baby**.

If you notice any cold-like symptoms within 6 months of giving birth, you should contact your study team immediately.

# Your Baby's Study Visit Schedule

| Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 |
|---|---|---|---|---|
| Baby's Birth | Baby is 6 weeks old | Baby is 4 months old | Baby is 6 months old | Baby is 1 year |
| | **1** blood draw (done randomly at Visit 2, 3 **or** 4) | | | |
| Physical exam<br><br>If no cord blood was collected: Blood draw<br><br>Medicine/ symptom review | Physical exam<br><br>Medicine/ symptom review | Physical exam<br><br>Medicine/ symptom review | Physical exam<br><br>Medicine/ symptom review | Physical exam<br><br>Medicine/ symptom review |
| **Your Visit 3** | **Your Visit 4** | | | |

The study team will **contact** you about **once a month** (**weekly** from about December to April) to **check on the health of you and your baby**.

Additional study visits may be required if you or your baby develops cold-like symptoms (e.g., runny/blocked nose, coughing or difficulty breathing).

# Thank You for Your Interest!

Contact the study team for more information:

***<Site Contact Name>***

***<Site Phone #>***

Please read the informed consent form for more information about the potential risks and benefits of participating in this study. You are also encouraged to speak with your doctor.