



## INFORMATION & AUTHORIZATION FORM

**RESEARCH TITLE:** A phase III, randomized, controlled, observer-blind study to demonstrate effectiveness, immunogenicity and safety of GSK's meningococcal Group B and combined ABCWY vaccines when administered to healthy adolescents and young adults.

**SHORT TITLE:** Effectiveness of GSK's Meningococcal Group B and Combined ABCWY Vaccines in Healthy Adolescents and Young Adults.

**PROTOCOL NUMBER:** 205416 [MENB REC 2ND GEN-038 (V72\_72)]

**RESEARCHERS:**

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**FUNDER:** GSK  
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**Introduction**

Your child is being invited to take part in this study. This research study will help us learn about vaccines protecting against diseases caused by different types of meningococcus germs (types A, B, C, W & Y).

Before a new vaccine can be marketed and given to the general public, it needs to be tested and then approved by national health agencies, such as Health Canada. Several studies are done to test the vaccine. The testing is done in 2 parts, testing in a laboratory, then testing how well the vaccine works in people. This is called a 'research study'. Health Canada, then looks at the results of these studies and approve the vaccine for use. All routine vaccines that you receive have been through this process.

You can decide if you want to let your child to take part in this study or not. Your choice will not change the quality of care that your child will receive outside of this study at the IWK Health Centre. Please take time to read the following information about the study. Feel free to ask any questions that you may have.

Informed consent means you agree to let your child take part in this study by signing this form. Before you decide, we want to make sure you understand what is involved. 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?**

Several different germs can cause a serious infection of the blood and nervous system. A germ (bacteria) called Meningococcus, also called *Neisseria meningitidis*, can cause several serious diseases, including meningitis and infection of the blood. Meningitis affects the brain and spinal cord. It can cause hearing loss, seizures, learning and behavior problems, severe brain damage and even death (death is caused in about half the cases if left untreated). Meningitis can happen to anyone but is more common in teenagers, and young children (including babies). This research study will help us learn about vaccines protecting against diseases caused by different types of meningococcus germs (types A, B, C, W, Y).

*Bexsero* is a vaccine intended to protect against the meningococcus B germ. This study will help us learn if this vaccine (*Bexsero*) is safe and helps protect against different kinds of meningitis B germs when given as 3 doses and 2 doses.

This research study will also test a new investigational vaccine called MenABCWY, to help us learn if it is safe and helps protect against 5 types of meningococcus germ - types A, B, C, W, and Y. Investigational vaccine means, this combined MenABCWY vaccine is experimental, has not yet been approved by the national health agency in Canada and has not been approved to be given to people except for research (like this study for example). So far, the vaccine has been given to approximately 1400 people aged 10 years and older in other studies.

The MenABCWY vaccine is made by combining 2 of GSK's already marketed vaccines, namely *Bexsero* and *Menveo*. *Bexsero* is a vaccine that helps to protect against the meningococcus B germ. *Menveo* is a vaccine that helps protect against types A, C, W and Y of the meningococcus germ. The use of *Bexsero* and *Menveo* has been approved in Canada as separate vaccines. *Bexsero* is approved for people aged 2 months through 25 years. *Menveo* is approved for use for people from age 2 months through 55 years. The investigational combined MenABCWY vaccine is being developed because it may reduce the number of different vaccines that need to be taken to protect against the 5 types of meningococcus germ.

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

This study is being done by doctors and research staff at the Canadian Center for Vaccinology (CCfV) located at the IWK Health Centre. The Principal Investigator, Dr. Joanne Langley is a Pediatric Infectious Disease Specialist. There will be about 3650 children, adolescents and adults aged 10 to 25 years across different countries including Canada taking part in this study. Approximately 25-50 adolescents will take part at CCfV in Halifax.

If your child joins this research study, he/she will get placed by chance in 1 of the 6 groups. A computer will be used to assign your child to a group by chance (like rolling dice). This is called randomization. Your child or the study doctor cannot choose a group.

Neither you/ your child nor the study doctor will know which vaccine/ injection your child will get. Other people involved in the study, such as the person giving the vaccine, will know which vaccine was given. This is done to avoid being influenced by knowing which vaccine your child received. The placebo is also given at certain visits for the same purpose. A placebo is an injection that does not have the main ingredient or medicine which may protect against meningitis infection. In this study it is a small amount of salt water.

You and the study doctor will be told what vaccines were given to your child only after the study has been completed or in case of a medical emergency.

The table below gives details on what vaccines your child will receive based on the group your child is assigned to:

	Visit 1 (Month 0)	Visit 3 (Month 2)	Visit 5 (Month 6)	Visit 6 (Month 7)
Vaccine Group A	<i>Bexsero</i>	<i>Bexsero</i>	<i>Bexsero</i>	<i>Menveo</i>
Vaccine Group B	<i>Bexsero</i>	<i>Menveo</i>	<i>Bexsero</i>	Placebo
Vaccine Group C	<i>MenABCWY-1</i>	Placebo	<i>MenABCWY-1</i>	Placebo
Vaccine Group D	<i>MenABCWY-2</i>	Placebo	<i>MenABCWY-2</i>	Placebo
Vaccine Group E	<i>MenABCWY-3</i>	Placebo	<i>MenABCWY-3</i>	Placebo
Vaccine Group F	<i>Menveo</i>	Placebo	<i>Bexsero</i>	<i>Bexsero</i>

*Bexsero* = Meningococcal B Vaccine

*Menveo* = Meningococcal ACWY Vaccine

*MenABCWY* = 3 Different Lots of the Study Vaccine

Placebo = Saline

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

Your child will have a total of 6 visits to the IWK and 7 phone calls over a 12 month period. This will take approximately 4-6 hours. Study visits may be performed at a different location other than the study site (e.g. at your home).

**Your child can take part in this study if:**

- He/she is healthy.
- He/she **has not received** the grade 7 - Men ACWY vaccine if currently in grade 7 or he/she has received a single Men ACWY vaccine at least 4 years before joining this study.
- He/she has not received a previous Men B vaccine at any age. (Your child can still join the study if a Meningitis C vaccine was received at or before 24 months of age)
- You and your child are able to understand the study and procedures, the risks and benefits involved, and agree to take part by signing the consent and assent form

**Your child will not be able to take part in this study if:**

- He/she have a confirmed or suspected problem with their immune system
- He/she is taking any medicines which may suppress their immune system
- He/she have previously had an allergic reaction to any vaccine being given in this study or any of their components

- He/she has a serious chronic or progressive medical condition

There may be other reasons why your child may not be allowed to take part in this study. The study doctor or staff will discuss this with you.

The following explains the various activities that will happen at each study visit:

**Consent & Eligibility** – At the first study visit we will review this study information and authorization form. If you agree to take part you will sign the form and receive a copy. Your child will also be asked to sign a form agreeing that they want to take part. We will make sure your child is eligible for the study by asking you questions about their health such as their medical history and any medications they take.

**Demographic Information** – We will collect your child’s date of birth, gender and race at the first study visit.

**Physical Exam** – Your child will have a physical exam. Measurement of blood pressure, heart rate and temperature will be done, and their height and weight will also be measured. Depending on your child’s medical history the doctor or nurse may also perform a more detailed assessment of different body parts (head, neck, thyroid, ears, eyes, nose, throat, chest, lungs, heart, lymph nodes, abdomen, skin, muscles and skeleton, nervous system and other if needed).

This is done to ensure your child is eligible to participate in this study. At the first visit this will be done for all. For the next visits: Visit 2, 3, 4, 5 and 6, the physical exam will be only done if the study doctor thinks it is necessary.

**Medical History** – At Visit 1, you will be asked to provide general information about your child, your child’s medical history and vaccination history.

At Visit 1 and at all visits and telephone calls, the study staff will ask about all medications including prescription medicines, over the counter medications, dietary supplements, vitamins and herbal medications your child is currently taking and may have taken recently in the past. If necessary, you may be requested to get medical records from other doctors.

**Blood Samples** – During the course of the study there are 4 blood samples (20-25 mL - about 4-5 teaspoons per sample). These samples will be taken to check your child’s antibody (protection) levels to Men ACWY & B. Blood is taken from your child’s arm using a small needle. Anesthetic cream to numb the pain can be used. We use other methods to decrease pain such as distraction. The samples will be taken by experienced pediatric staff.

If your child was given antibiotics within three days of the blood sample collection, the visit (including the blood draw) will be moved to a later date. If this happens, the study team will tell you when to bring your child back in.

**Vaccination** – If your child is eligible to take part in the study, he/she will receive 4 injections at the first study visit, Month 2, Month 6 & Month 7.

The vaccine will be given in the upper arm muscle. After the injection, your child will be observed for at least 30 minutes to monitor your child for any type of rare allergic reaction.

If your child is currently in grade 7 they should still receive the other routine school based vaccines from the Public Health Nurse. We will send a record of the vaccinations to your family doctor and Public Health.

Your child's vaccination may be moved to a later date in case your child had acute illnesses with fever (38.0°C/100.4°F) in the 7 days before the vaccination.

**Diary Card** – You will be asked to report certain information after your child has got the vaccine/product on an individual electronic diary. This diary reminds you to report specific types of side effects that are looked for after vaccine /product administration. The diary used in this research study is an electronic device.

The site staff will give you the electronic diary (called eDiary) and will explain how to use it and make entries for up to 30 days after the vaccine/product is given. You will also be asked to:

- Look at the place where your child got the study vaccine and measure specific reactions you may see.
- Indicate if your child experiences other kinds of reactions that are sometimes seen after study vaccine, such as fever, nausea (feeling the need to vomit), fatigue (tiredness), muscle pain, aching in several joints and headache.
- Measure your child's body temperature preferably by mouth.
- Call the site staff if your child experiences symptoms that concern you or need you to visit a doctor or medical professional.
- Bring the eDiary with you at your child's next visit, as relevant.

The electronic diary device's in-built audio-visual alarms will also alert you to complete the diary during the period after vaccination.

**Phone Calls** – You will receive a total of 7 telephone calls during the course of the study. The study staff will call you to review your child's general health status, such as any visits to the doctor for any new and/or serious health problems since the last vaccination/ last visit to the study center/ last phone call. The phone calls can be expected at the following time points:

- Around 15 days after your child's study vaccine at Visit 1 and Visit 3 and Visit 5 (totally 3 phone calls).
- Around 60 days after Visit 3 and Visit 5 (2 phone calls).
- Around 4 months after Visit 5 (1 phone call).
- The last phone call will be made around 6 months after Visit 5. This phone call will mark the study end.

**Urine Pregnancy Test and Contraception** – The effects of the study vaccine on an unborn baby are not well known. Therefore, your daughter cannot take part in this research study if she is pregnant or breastfeeding.

Your daughter will have a urine pregnancy test if she has reached puberty (childbearing potential) before she can receive any study vaccination.

If you choose to let your daughter take part in this research study, she must use at least one of the acceptable methods of birth control listed below during this research study (so that she does not become pregnant).

- Avoid having sex.
- Protective (also called contraceptive) implant.
- Birth control devices (such as intrauterine devices).
- Birth control pills.

The birth control has to be practiced from 30 days prior to first vaccination to 30 days after completion of all vaccinations (30 days before Visit 1 to 30 days after Visit 6).

You can discuss these various options with the study doctor. If you have any questions on acceptable birth control methods, please consult your doctor.

In case, your daughter gets pregnant during the study, tell the study doctor immediately. Your daughter will not receive any more study vaccinations, but she will be followed-up for her and her baby’s safety. We will collect certain information from your daughter such as your general health during pregnancy, the outcome of your pregnancy and the general health of your daughter’s baby (for around 6 to 8 weeks from estimated delivery date).

What happens during each visit is summarized in the table below:

Visit Day	Visit Details
<b>Visit 1</b> <b>(Day 1)</b> Time: 60-75 minutes	<ul style="list-style-type: none"> <li>- Informed consent and assent</li> <li>- Medical history, demographic information &amp; review study eligibility</li> <li>- Physical examination</li> <li>- Urine pregnancy test (for females of childbearing age)</li> <li>- <b>Blood sample</b> – approximately 20 mL (about 4 teaspoons)</li> <li>- Randomization &amp; <b><u>Vaccination</u></b></li> <li>- 30 minute wait</li> <li>- Receive eDiary and instructions and record information</li> <li>- Phone Call 1 (15 days later)</li> </ul>
<b>Visit 2</b> <b>(Month 1)</b> Time: 15-30 minutes	<ul style="list-style-type: none"> <li>- Reconfirm study consent and eligibility</li> <li>- Record medical history and medication</li> <li>- Review eDiary</li> <li>- Physical examination (if needed)</li> <li>- <b>Blood sample</b> – approximately 25 mL (about 5 teaspoons)</li> </ul>
<b>Visit 3</b> <b>(Month 2)</b> Time: 45-60 minutes	<ul style="list-style-type: none"> <li>- Reconfirm consent and eligibility</li> <li>- Record medical history and medication</li> <li>- Record information on the eDiary</li> <li>- Physical examination (if needed)</li> <li>- Urine pregnancy test (for females of childbearing age)</li> <li>- Measure temperature</li> <li>- <b><u>Vaccination</u></b></li> <li>- 30 minute wait</li> <li>- Phone Call 2 (15 days later)</li> </ul>
<b>Visit 4</b>	<ul style="list-style-type: none"> <li>- Reconfirm study consent and eligibility</li> </ul>

<b>(Month 3)</b> Time: 15-30 minutes	<ul style="list-style-type: none"> <li>- Record medical history and medication</li> <li>- Review eDiary</li> <li>- Physical examination (if needed)</li> <li>- <b>Blood sample</b> – approximately 25 mL (about 5 teaspoons)</li> </ul>
<b>Phone Call 3</b> <b>(Month 4)</b> Time: 5 minutes	<ul style="list-style-type: none"> <li>- Record any changes in health or new medications</li> </ul>
<b>Visit 5</b> <b>(Month 6)</b> Time: 45-60 minutes	<ul style="list-style-type: none"> <li>- Reconfirm consent and eligibility</li> <li>- Record medical history and medication</li> <li>- Record information on the eDiary</li> <li>- Physical examination (if needed)</li> <li>- Urine pregnancy test (for females of childbearing age)</li> <li>- Measure temperature</li> <li>- <b><u>Vaccination</u></b></li> <li>- 30 minute wait</li> <li>- Phone Call 4 (15 days later)</li> </ul>
<b>Visit 6</b> <b>(Month 7)</b> Time: 45-60 minutes	<ul style="list-style-type: none"> <li>- Reconfirm study consent and eligibility</li> <li>- Record medical history and medication</li> <li>- Review eDiary</li> <li>- Physical examination (if needed)</li> <li>- Urine pregnancy test (for females of childbearing age)</li> <li>- Measure temperature</li> <li>- <b>Blood sample</b> – approximately 25 mL (about 5 teaspoons)</li> <li>- <b><u>Vaccination</u></b></li> <li>- 30 minute wait</li> </ul>
<b>Phone Calls 5-7</b> <b>(Months 8, 10, 12)</b> Time: 5 minutes/call	<ul style="list-style-type: none"> <li>- Record any changes in health or new medications</li> </ul>

**What are the burdens, harms, and potential harms?**

Like all medicines and vaccines, the study vaccines may cause side effects – although not everyone gets them. A side effect is an unwanted medical event that may have been caused by the study vaccine. 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. Call the study doctor if there are any changes to your child’s health that concern you.

Below, we have listed the side effects and risks that we know about. Others could happen as well. Ask the study doctor if you have any questions about the possible risks or side effects.

**Possible side effects with *Bexsero***

**Infants and children (up to 10 years of age):**

**Very common** (may happen in more than 1 in 10 people): fever greater than or equal to 100.4°F (38° C), loss of appetite, tenderness at the injection site (including severe injection site tenderness), painful joints, sleepiness, feeling irritable, unusual crying, vomiting (uncommon after booster), diarrhea, headache

**Common** (may happen in up to 1 in 10 people): skin rash

**Uncommon** (may happen in up to 1 in 100 people): high fever, 104°F (40°C) or greater, seizures (including febrile seizures), dry skin, paleness (rare after booster)

**Rare** (may happen in up to 1 in 1000 people): Kawasaki disease which can have symptoms such as fever that lasts for more than five days, associated with a skin rash that can be itchy on the trunk of the body, and sometimes followed by a peeling of the skin on the hands and fingers, swollen glands in the neck, red eyes, lips, throat and tongue

**Adolescents (from 11 years of age) and Adults:**

**Very common** (may happen in more than 1 in 10 people): pain at the injection site (including severe injection site pain resulting in inability to perform normal daily activity), painful muscles and joints, nausea (feeling the need to vomit), generally feeling unwell, headache,

**Other side effects (all age groups):**

The following side effects have also been reported but because they were voluntarily reported after the vaccine was released, we can't tell how often they occur or if they are related to the vaccines:

- Allergic reactions that may include severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing), difficulty breathing with wheezing or coughing, rash, loss of consciousness and very low blood pressure;
- Fainting or collapsing, less responsive than usual or lack of awareness, and paleness or bluish skin discoloration in young children; feeling faint or fainting;
- Skin rash (adolescents from 11 years of age and adults)
- Fever (adolescents from 11 years of age and adults); injection site reactions like extensive swelling of the vaccinated limb, blisters at or around the injection site and hard lump at the injection site (which may last for more than one month).

**Possible Side Effects with MenABCWY vaccine**

**Adolescents (from 10 years of age) and Adults:**

**Very common** (may happen in more than 1 in 10 people): pain and hardening of the skin at the injection site, redness at injection site, painful muscles, nausea (feeling the need to vomit), loss of appetite, generally feeling unwell, headache, chills, fatigue (tiredness).

**Common** (may happen in up to 1 in 10 people): fever greater than or equal to 100.4°F (38°C), painful joints, rash.

**Possible Side Effects with Menveo**

**Children 2 to 10 years of age:**

**Very common** (may happen in more than 1 in 10 people): sleepiness, headache, irritability, a general feeling of discomfort, injection site pain, injection site redness (less than or equal to 50 mm), hardening of the skin at injection site (less than or equal to 50 mm)

**Common** (may happen in up to 1 in 10 people): eating disorder, nausea (feeling the need to vomit), vomiting, diarrhea, rash, joint pain, muscle pain, injection site redness (more than 50mm), hardening of the skin at injection site (more than 50mm), chills, fever equal to or more than 100.4°F (38°C).

**Uncommon** (may happen in up to 1 in 100 people): itchiness at the injection site.



**Adolescents (from 11 years of age) and Adults:**

**Very common** (may happen in more than 1 in 10 people): headache, nausea (feeling the need to vomit), muscle pain, injection site pain, injection site redness (less than or equal to 50 mm), hardening of the skin at injection site (less than or equal to 50 mm), a general feeling of discomfort.

**Common** (may happen in up to 1 in 10 people): rash, joint pain, injection site redness (more than 50mm), hardening of the skin at injection site (more than 50mm), chills, fever equal to or more than 100.4°F (38°C).

**Uncommon** (may happen in up to 1 in 100 people): dizziness, itchiness at the injection site.

**Other side effects (all age groups):**

The following side effects have also been reported but because they were voluntarily reported after the vaccine was released, we can't tell how often they occur or if they are related to the vaccine:

- enlarged lymph nodes near injection site
- allergic reactions that may include skin rash, severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing), difficulty breathing with wheezing or coughing, loss of consciousness and very low blood pressure;
- feeling dizzy even when sitting or lying down
- numbness and weakness of the face, drooping of the eyelid, difficulty in hearing, ear pain, vertigo and dizziness
- loss of consciousness with severe muscle contractions, seizures due to fever
- pain while swallowing, sore mouth
- skin blisters
- bone pain
- injection site swelling, including extensive swelling of the injected limb, tiredness
- abnormalities in blood tests for liver function
- fall, head injury

**Other risks in the study**

**Placebo**

The use of placebo does not usually cause side effects other than the ones known for any injection.

**Possible risks from injections**

Pain, redness, soreness, itchiness, swelling, or bruising. There is a very small chance of infection.

**Blood sampling**

When your child gives blood, they may feel faint, or experience mild pain, bruising, irritation or redness at the site where the blood was taken. Blood is taken from your child's arm using a small needle. Anesthetic cream to numb the pain may be used. We use other methods to decrease pain such as distraction. The samples will be taken by experienced pediatric staff.

**Allergic Reaction**

With any vaccine an allergic reaction with itching and a rash is possible. Rarely, allergic reactions may be severe, with sudden onset of symptoms such as redness, fast heart rate, swelling of the face, trouble breathing and swallowing or sudden drop in blood pressure. These usually happen shortly after

receiving a vaccine. These allergic reactions can be life threatening; therefore, the study staff will watch your child for about 30 minutes after each vaccination.

**Latex** - If your child is allergic to latex, he/she should not receive the vaccine.

**Allergy** - Your child should not receive any of the above-mentioned study vaccines, if he/she had an allergic reaction (hypersensitivity) to any of the components of the study vaccines.

Rarely, children who receive vaccines might develop illnesses called autoimmune diseases. Autoimmune diseases have also occurred in people who have not been vaccinated. These diseases develop when immune cells that normally protect you from illness, attack your organs instead. Autoimmune diseases can be serious and can also be lifelong. They can involve your liver, kidneys, skin, joints, eyes, brain, as well as other parts of the body. Since no one knows for sure if vaccines might cause autoimmune diseases, GSK continues to monitor this situation closely.

**Call the study staff right away if your child has any side effects that you think are serious.**

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

There may or may not be a direct medical benefit to your child if he/she take part in this study.

- If your child receives *Bexsero* and *Menveo*, *Bexsero* might protect against diseases caused by the meningitis germ type B and *Menveo* might protect against diseases caused by the meningitis germ types A, C, W and Y.
- If your child receives the MenABCWY vaccine, it might protect against the diseases caused by all 5 types of meningitis germ (A, B, C, W, Y) as a single combined vaccine.

This study may also help us learn more about meningococcal diseases, the effects of *Bexsero* and the investigational vaccine MenABCWY and how well they work.

By taking part, your child may help make new or improve existing vaccine(s) to protect people against diseases caused by meningitis germ.

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

Your child does not have to participate in this study. This study is for research purposes. If your child is in grade 7 and does not take part in this study they can receive the routine Men ACWY vaccine from the Public Health Nurse at school. This is only 1 injection as opposed to 4 injections as part of the study.

*Bexsero* can be purchased. You can ask you family doctor or pharmacist if you are interested in receiving this vaccine for your child.

There is no combined vaccine available in the market that may help protect against all the 5 meningococcus germ types A, B, C, W and Y in 1 injection.

### **Communication of new information**

The study doctor will tell you if there is any new information that might change your choice to keep your child in the research study. The study doctor will tell you if a new vaccine or treatment for meningococcal disease becomes available in your country during this study. You can then decide if you wish that your child leaves 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 let your child stay in the study will be shared and discussed with you as soon as possible.

Also, GSK, the health agencies, or the study doctor may choose to stop the research at any time. If something does change, the study doctor will tell you as soon as possible.

**Can I withdraw from the study?**

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

Your child can leave the study at any time. You do not have to give a reason if you choose to withdraw your child from the study. Tell the study doctor if you no longer want your child to take part. Your choice will not change the quality of care your child would receive outside of this study.

If you decide to withdraw your child from this study, all the data and samples collected while your child was 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 child's health after your child has left the study. If this information relates to the safety of the vaccine your child received during the study, the study doctor will send it to GSK.

**Can your child be asked to leave the study?**

Your child may be asked to leave the study if:

- Test results show that this study is not right for your child.
- You or your child do not follow the study instructions.
- The study doctor thinks it is best for your child to leave, for example if your child develops specific health problems.
- The entire study needs to be stopped for everyone due to other circumstances that cannot be predicted.

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, parents will receive \$25 per visit and a parking pass at the end of each visit if required (if you park in the IWK parking garage). Children will receive a \$25 gift card at each study visit.

Parents will receive \$150 in total (\$100 will be paid out after study visit #4, \$50 will be paid out after study visit #6). Payment to parents will be made by cheque through Dalhousie University. You will be asked to sign a form to receive the cheque. If for any reason your child does 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 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 lead to a change in approvals for how the vaccine is used after the study is completed, you will not receive any of the financial benefits.

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

The group study results and your child's individual results can be made available to you once the study is completed and reported. This may take many months after the study has been completed. The results will be mailed to you if you want to receive them. You will be asked to initial the last page of this form indicating if you wish to receive the results. It will be important that you notify us if there is any change in your address, so we are able to contact you with study results. We will post a summary of the overall results on the CCfV website and publish the results in the medical literature.

**What will happen to my child's study samples?**

As part of the study, your child's blood samples will be taken. Your child's samples will be given a unique code number. The code number will not identify your child directly and will not have your child's personal information (data).

If your daughter is of childbearing age, your daughter will be asked to give a urine sample before each vaccination for testing to confirm that she is not pregnant. These samples will be discarded after testing for pregnancy.

Your child's blood 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 child's samples will be tested to look at how your child's body reacts to the study vaccines. Depending on the group your child is assigned to, some of the blood samples collected may not be used for any testing related to this study. However, these samples may be used for further research related or NOT related to the study vaccines and/or disease. This has been explained in detail in the next section (What will happen to your personal information (data)? - OPTIONAL USE OF SAMPLES AND CODED DATA).

Your child's 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 vaccines or disease is maintained over time,
- Develop and improve tests related to the study vaccines or disease.

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

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

**What are my research rights?**

Your signature on this form only indicates that you have understood to your satisfaction the information regarding your child's participation in the study and agree to have them 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 your child 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. You are free to withdraw from the study at any time without jeopardizing the health care you are entitled to receive.

If you have any questions at any time during or after the study about research in general or your rights as a participant, you may contact the Research Office of the IWK Health Centre at 902-470-7879, Monday to Friday between 8 am and 4 pm.

### **How will my child's privacy be protected?**

The study doctor and other study staff will collect data that can identify your child. This may include your name/ your child's name, address, phone number and past treatment history. Personal health information will be collected as part of the study. All your child's personal information collected for this study will be stored in the study medical records at the study site, but will be kept separate from other medical records. GSK staff, review boards and ethics committees (that approve and monitor studies), and others may check the study records. This is done to make sure that the study is carried out in compliance with legal and quality requirements. For this purpose, personnel acting on behalf of the sponsor may view your child's data at study site or by using protected multimedia tools (e.g. video or uploading your documents to a computer system). Appropriate measures will be taken to protect your child's personal information. No information directly identifying you/your child (e.g. name, address, phone number) will be retained by GSK staff or others acting on behalf of GSK.

During this study, your child will be assigned a unique code number. Your child's data will be collected and shared only in relation to this code number. Once collected, either on site or at your home, data that directly identifies your child will not leave the study site or be sent to GSK.

The data collected about your child will be held by at the study site and coded data will be held by GSK and/or third parties working on behalf of GSK and/or institutions working with GSK. GSK will protect all data collected about your child 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 vaccines administered and related diseases.

At times, GSK may need to anonymize your child's data. This means your child's code number can no longer be linked to your child. 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 child's data as described in this form, your child cannot join this study.

### **Why will your child's data be collected?**

Various data related to your child's 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 child's data will be coded and handled as described earlier in this form.

### Who will be able to see your child's data?

Your child's 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 child's data. This is so that they can verify clinical trial procedures and/or data.

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

### What happens if your child's data is transferred?

Your child's 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 the laws in your home country. 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 child's data?

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

- To learn more about what is done with your child's data.
- A copy of your child's data.
- To correct and/or delete your child's data.
- To transfer your child's 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 child's data.
- Complain to your child's local data protection authority, if your child's privacy rights are violated.
- Claim compensation for damages caused due to unlawful use of your child's data, through the courts.

In some circumstances while the study is still in progress, you may not be given access to your child's personal information that is related to the study, in order to protect the integrity of the study.

### How long will your child's data be used?

Your child's 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.

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.

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.

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 your child. At most, the website will include a summary of the results. You can search this website at any time.

Who will collect and process your child's 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.




Who owns the study results?

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/Your child will not be paid any part of this. The investigator/institute is being paid to conduct the study.

Whom should you contact if you have any questions?

For questions or requests regarding what is done to your/your child's 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](mailto:EU-DPO@gsk.com).

What happens to your child's data?

At study site	 <p><b>Personally identifiable information</b></p> <p>These data are collected by the study staff to identify and contact you. The data are stored in the study medical records at the study site. GSK staff (e.g. study monitors), IRBs/IECs and others may check the study records. The study records are never sent to GSK.</p> <p><i>Examples: your name, address, e-mail, phone number</i></p>
At GSK	 <p><b>Coded data</b></p> <p>All your data that will be sent to GSK will be coded. This means that GSK will not be able to link the data with you. The code list is kept secure and confidential by the study site. If needed, GSK can ask the study doctor to make the link with you.</p> <p><i>Examples: data about your health after vaccination, results from tests of your bloods samples etc.</i></p>
At GSK and beyond	 <p><b>Anonymised data</b></p> <p>When the code list is destroyed, your data is "anonymised". Once your data are anonymised, it can no longer be linked to you by the study staff or GSK. All personal identifiers would be completely removed.</p>

## OPTIONAL USE OF SAMPLES AND CODED DATA

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

- Further research related to the study vaccines and/or disease. This means additional studies conducted to understand the study vaccines and/or disease better.
- Further research NOT related to the study vaccines and/or diseases. 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, your child can still join the study. You will be asked to indicate your choice on the signature page.

### What happens during special circumstances like COVID-19 pandemic?

Some study procedures that may be adapted to ensure your child's safety during special situations like the ongoing Coronavirus disease 2019 (COVID-19) pandemic.

**Government and health authorities have issued advice and imposed certain restrictions to control the COVID-19 pandemic. It is important that you follow all official advice.**

### **What impact can these special situations have on the study procedures?**

- Some of the planned visits to the research site/clinic/hospital may be replaced by a telephone call, email, or other modes of virtual contacts.
- The study staff may visit your home for any of the visits, upon your agreement, to:
  - Take your child's blood sample.
  - Take your daughter's urine sample, if your daughter is of childbearing age.
  - Give the vaccine dose.



- Check for any health problems before and after your child receive(s) the vaccine or give(s) a blood sample.

### **What should you do if you suspect your child has COVID-19 infection?**

The most common symptoms of COVID-19 include fever, cough and difficulty in breathing or shortness of breath. If your child feels unwell or have any of the above symptoms, contact public health officials right away. We ask that you also please report this to the study staff.

Prior to and at each study visit we will ask questions to see if you have any symptoms suggestive of COVID-19, recent travel or exposures. We will provide instructions on how to access CCfV to attend the study visits and whether or not you will be required to wear any personal protective equipment (PPE). If required, PPE will be provided. CCfV follows the guidance of the IWK Health Centre and Nova Scotia Public Health.

Study staff will not conduct visits if your child or anyone in your household has any COVID-19 symptoms, recent travel or exposures.

### **Contact for future studies**

You will be asked at the end of the study if we can contact your child for future related studies. If you agree to be contacted, it does not mean that your child has 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 child's name, address, phone number and date 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 Research Nurse Coordinator, Jill Mutch, at (902)470-3860 or [jill.mutch@iwk.nshealth.ca](mailto:jill.mutch@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.

**PARTICIPANT NUMBER:** \_\_\_\_\_

**Study Title:** A phase III, randomized, controlled, observer-blind study to demonstrate effectiveness, immunogenicity and safety of GSK's meningococcal Group B and combined ABCWY vaccines when administered to healthy adolescents and young adults.



**Participant Authorization**

I have read or had read to me all pages of this information and authorization form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I have been given enough time to make a decision. I understand the nature of the study and I understand the potential risks. I understand that my child's information and samples will be used as described in this form. I understand that I have the right to withdraw my child from the study at any time without affecting their care in any way. I have received a copy of the Information and Authorization Form for future reference. I freely agree to let my child participate in this research study.

A Legally Acceptable Representative (LAR) of an individual would typically be a parent with custody or an appointed legal guardian with custody. By signing this consent you are confirming that you are the Legally Acceptable Representative for the above individual. If there is any question about who is the most appropriate Legally Acceptable Representative, please speak to the Study investigator or coordinator before signing this document.

Name of Participant: (Print) \_\_\_\_\_

\_\_\_\_\_  
Name of Parent/LAR (Print)

\_\_\_\_\_  
Signature of Parent/LAR

Relationship to the Participant: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

I would like to receive a copy of the study results when available. Circle: Yes or No: Initial \_\_\_\_\_

I agree that the study staff may inform my child's family doctor of my child's study participation. Circle: Yes or No: Initial \_\_\_\_\_

I agree to be contacted and given information about future studies. Circle: Yes or No: Initial \_\_\_\_\_

I agree that my child's samples and coded data can be used for further research related to the study vaccines and/or diseases once the study is complete. Circle: Yes or No: Initial \_\_\_\_\_

I agree that my child's samples and coded data can be used for further research NOT related to the study vaccines and/or diseases, once the study is complete. 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's parent/LAR and judge that they understand that participation is voluntary and that they may withdraw their child at any time from participating.

Name (Print): \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_