CONFIDENTIAL

Oxford Vaccine Group
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Centre for Clinical Vaccinology and Tropical Medicine,
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PARTICIPANT AND PARENT/ CARER INFORMATION SHEET AND INFORMED CONSENT FORM

Study title: A Phase 3 study to assess the immune response and safety of rMenB+OMV NZ in primed healthy participants (10 to 20 years old)	
Study identification:	220030
Abbreviated title	MENB REC 2ND GEN-096 BST:002,055,058
EU CT number	2024-519549-31
Name of company sponsoring the study:	**GlaxoSmithKline Biologicals SA**
Study participant ID	
Name of study doctor:	**Dr Simon Drysdale**
Address of research site:	**Oxford Vaccine Group**
Phone number:	**01865 611400**

You are invited to take part /let your child take part in this research study.

This study is conducted by GSK. GSK is a company that discovers and makes vaccines, medicines, and other healthcare products. GSK is the sponsor of this study and pays research site to take part in this study.

This consent form describes the study and what taking part in the study means for you/your child.

The study staff will explain the study and the information in this consent form to you. Please ask about anything you do not understand.

Your decision to take part/let your child take part in this study is voluntary. It is completely up to you. You can change your decision and leave/withdraw your child the study at any time without giving a reason.

Before you decide to join/let you child join the study, you may talk to other people you feel comfortable with such as family, friends, or your GP (General Practitioner)/ your

child's GP about your/your child's participation. Please take as much time as you need to make your decision.

The study has been reviewed and approved by a Medicines and Healthcare products Regulatory Agency (MHRA). Research Ethics Committees (RECs) protect the rights, safety and well-being of people who take part in research studies. If changes are required to be made on the approved ICF, the REC will be also requested to review and approve the changes to support the protection of participants, involved in this trial.

What is the purpose of this study?

The study vaccine is a GSK vaccine given to protect against a germ (bacterium) called Meningococcus. The Meningococcus bacterium (also called *Neisseria meningitidis*), can cause several serious diseases, including meningitis and infection of the blood. Meningitis affects the protective membranes around the brain and spinal cord. It can cause hearing loss, seizures, learning and behaviour 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 more about *Bexsero*, which is a vaccine intended to protect against the meningococcus B germ.

This study, in particular, will help us learn how safe and effective a booster jab (an extra dose) of a vaccine called *Bexsero* is for older kids, teenagers, and young adults, specifically those aged 10 to 20 years. *Bexsero* has been approved for use in the United Kingdom, and is available as one vaccination against the meningococcus B germ. Therefore you won't need the medication after the trial, if the booster jab will be approved, you will also be able to get a booster in your GP surgery.

You/your child may or may not have already received this vaccine as a baby; now, since you/your child have/has grown older, this study will help us determine if a booster jab improves your/your child's immunity even more.

Approximately 312 children, adolescents and adults aged 10 to 20 years, across different countries including UK will take part in this study. The study will last for approximately 1 month for each participant.

Which vaccine will you/your child get?

If you/your child join(s) this study, you/your child will be assigned to either one of the following two groups, based on whether you/your child received the *Bexsero* vaccine as

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a baby:

- **Primed group**: If you/your child already received the *Bexsero* vaccine as a baby, you/your child will be in the "primed group", i.e., you/ your child will receive only one jab of the booster vaccine.
- **Naïve group**: If you/your child have/has never received the *Bexsero* vaccine or any other vaccine against the meningococcus B germ before, you/your child will be in the "Naïve group", i.e., you/your child will receive two jabs of the *Bexsero* vaccine. You/your child will receive the first jab on the first visit, followed by another one approximately 1 month later.

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

	Visit 1 (Day 1)	**Visit 2 (Day 31)**
Primed group	*Bexsero*	
Naïve group	*Bexsero*	*Bexsero*

The effects of the first dose of vaccine, both good and bad, will be compared.

Both you/ your child and the study doctor will know how many doses of vaccine you/ your child will get.

What do you/ your child need(s) to do in this study?

If you choose/choose to let your child to take part in this study, you will need to sign the signature page at the end of this form. You will receive a copy of it.

You/ your child will have to follow the study doctor's and study staff's instructions and tell them about any changes to your/your child's health during the study.

If you agree, the study doctor may tell your GP /your child's GP that you are/your child is taking part in a study and provide the study related information.

Tell the study doctor if you are/your child is currently in another drug or vaccine or medical device or observational research study. You/your child cannot be in another drug or vaccine or medical device research study while taking part in this study.

If you agree to join/agree to let your child join this study, you agree to the following:

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You/ your child will receive a subject card with study contact information. Keep this card with you at all times during the study. Show this card to the medical staff if you/ your child need emergency care during the study. The medical staff can then contact your study team if needed to ask about the vaccine you/ your child received.

Follow the study doctor's and study staff's instructions. You/your child will need come to the clinic approximately 2 times.

At the first visit, you will be asked if you/your child has previously received the *Bexsero* vaccine (or any Meningococal B or MenACWY vaccines). Tell the study doctor about any medicines and other vaccines or treatments you/your child may have taken recently in the past.

Unplanned contact via telephone may need to be done for safety reasons. In addition, the study doctor/study staff may contact you (or your designated contact, if applicable) at other times during the study if needed, to find out how you are/your child is.

As explained above under "**Which vaccine will you/your child get?**", you/your child will be administered the study vaccine as follows:

- If you are/your child is in the "**Primed group**" (i.e., you/your child already received the *Bexsero* vaccine as a baby) you/your child will receive only one jab of the booster vaccine during the first visit.
- If you are/your child is in the "**Naïve group**" (i.e., you/your child have/has never received the *Bexsero* vaccine before) you/your child will receive the first jab on the first visit, followed by another one approximately 1 month later.

After each study vaccine/product administration, you/your child must stay in the office for about 30 minutes so that the study doctor or his/her staff can see whether you have/your child has any side effects from the study vaccine/product. During this time, the staff will ask questions and may examine you/your child. The site will also give you instructions for what to do after you/your child leave the clinic and when to return to the clinic next. The study staff will train you/ your child on how to use and enter information in the eDiary app/ device during this time.

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A blood sample will be taken 2 times (approximately 20 ml at each visit) during the study . Repeat or unplanned samples may need to be taken for safety reasons or if there are technical issues with the samples.

Before each vaccine administration, you/your child's body temperature will be measured.

If you are a woman who can get pregnant/ your daughter can get pregnant, you/your daughter will be asked to give a urine sample before you/your daughter get(s) the vaccine. This sample will be tested to make sure that you are/ your daughter is not pregnant.

After first vaccine dose you will be given an electronic diary (like a mobile phone) to complete on site or to take home with you. You/ Your child will answer questions about how you/your child feel(s) and function(s), and/or be asked to enter the side effects that you/your child experience(s) after receiving the vaccine.

The electronic device has an automatic alarm that will alert you to complete the diary during the period required by the study (e.g., every evening), and/or after receiving the vaccine.

You may be asked to use an eDiary study application (an app) to collect data away from the study site throughout the course of the study. Use of the app is mandatory if you are/ your child is using your own mobile phone or device. You may be asked to download the app on your own phone or device, or if you don't have a suitable device to download the app the sponsor will provide you with a device. This device will be locked, so no other applications can be installed. The device will have to be returned to your study site after your/ your child's participation in the trial. Please inform your study team immediately if the device stops working or gets lost. You will be asked to read the app's Privacy Policy. The app's Privacy Policy will provide information about what personal data is collected, how it is used and whom it is shared with. It is important that you read and understand this notice.

If you object to how your data/ your child's data is processed by the app, you may no longer have access to the app, and this could impact your/ your child's participation in the trial. There may be updates to the notice during your/ your child's participation in the study. If this happens, you will be presented with the new information and asked to read the new terms.

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Figure 1 Schedule of events:

Study duration: Approximately 1 month

	Visit 1	**Visit 2**
	Day 1	**Day 31**
Physical exam^		
Blood draw		
Urine sample^^		
Vaccination*		
Review/return of electronic diary†		

^ Physical examination at Visit 2 will be done only if the study doctor thinks this is necessary

^^ Urine sample collection will happen before vaccination for female participants. (Please refer to section "What about pregnancy and breastfeeding?)

* During Visit 1, both groups (Primed group as well as Naïve group) will receive the vaccine, while at Visit 2, only the Naïve group will receive the vaccine.

† The eDiary will be distributed on Day 1/Visit 1. The eDiary should be returned on Day 31/Visit 2 if you are using the eDiary device distributed by the study site.

Before taking part, you should consider if this will affect any insurance you/ your child currently have or may purchase in the future. Seek advice if necessary from your/ your child's insurance company.

Please note that the first visit may take between 1-2.5 hours, due to the tasks your/ your child's study team will have to perform in the background. The second visit will be as long as a usual doctors appointment.

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What do I need to know about the eDiary platform?

A secure platform called IQVIA eCOA (electronic clinical outcome assessment) will be used in this study. The Sponsor is working with IQVIA RDS, Inc. to include eCOA to support this study. IQVIA is a human data company that works together with the sponsor to conduct this study.

The study will be using a secure website (My Study -the eCOA portal) and the IQVIA Scribe Application (App). The IQVIA Scribe App will allow you to have access to study diaries and questionnaires. The study team can tell you more about this.

You will access eCOA using a secure app on your smartphone or tablet or a dedicated smart phone provided by the study team. To access eCOA you will need to download the IQVIA Scribe App. The study team will assist with downloading the app as well as the creation of your account.

Once all your/ your child's study activities have been completed or you/ your child's have withdrawn from the study, you can remove the IQVIA Scribe application from your phone by following your device's standard procedures for removing applications. If you were provided with a device from the study team, you will need to return it at the end of the study. You can contact the study team if you need assistance with this.

Your/ Your child's records will be kept secure during the course of the study. Only the minimal amount of your/ your child's personal data necessary to conduct this study will be collected in eCOA. For most purposes, your data/ your child's data will only be accessible in an anonymised form. This means that the people working with your data/ your child's data will never learn your/ your child's full name. IQVIA and IQVIA's entities with which IQVIA contracts to provide services for the study will have access to your/ your child's anonymised information as described in this informed consent.

The eCOA Customer Care team will create your /your child's account in eCOA using a mock email address. All the data collected about you/ your child in eCOA will be identified only by your/ your child's participant number. Only your/ your child's study doctor and the study team (including the eCOA team on behalf of the study team) will have access to your answers to the diaries or questionnaires; this information will not be shared outside of the eCOA portal unless necessary for safety purposes.

The study team will also collect, record, and use personal information about you/ your child, for study purposes only, within eCOA, which is a secure internet portal. Your/ your child personal information collected in eCOA may include:

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- Health Information from the questionnaires you are asked to complete

The study doctor can provide you with more information about eCOA and the data collected.

If you have questions or concerns about your/ your child's personal data or exercising your/ your child's data subject rights, please reach out to GSK's Data Privacy Officer at EU.DPO@gsk.com.You also have the opportunity to reach out to your local data protection authority, which you can find here: Information Commissioner's Office under https://ico.org.uk/

What potential benefits can you/your child expect?

There may or may not be direct benefit for you/your child in taking part in this study

This study may also help us learn more about the meningitis B germ, the effects of the *Bexsero* booster doses and how well they work.

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

During this study, you/your child will also have medical history directed health check-ups.

What potential side effects or risks can you /your child expect?

A side effect is an unwanted medical event that may have been caused by the study drug/vaccine. Like all medicines and vaccines, *Bexsero* may cause side effects – although not everyone gets them.

We do not know all the side effects that may happen. It is possible that new and previously unknown side effects could be serious or even life-threatening. Everyone taking part in the study will be observed carefully for any side effects.

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Call the study doctor immediately if you/ your child get any side effects that concern you/your child.

Possible risks from giving blood: You/your child may feel faint, have mild pain, bruising, irritation or redness from the needle.

Possible risks from injections: Pain, redness, soreness, itchiness, swelling, or bruising. There is a very small chance of infection.

Possible risks from any vaccine: Headache, fever, feeling tired, nausea (feeling the need to vomit), vomiting, diarrhoea (runny stools that occur more often than usual) or abdominal pain. You/your child may feel pain, redness and swelling where the injection is given.

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 you/ your child for about 30 minutes after each vaccination.

The following side effects are expected with *Bexsero* .

All age groups

When Bexsero is given to you or your child, the very common side effects (may affect more than 1 in 10 people) that you or your child may get (reported in all age groups) are: pain/tenderness at the injection site, redness of the skin at the injection site, swelling of the skin at the injection site, hardness of the skin at the injection site.

The following side effects may also occur after receiving this vaccine:

Children (up to 10 years of age)

Very common (may happen in more than 1 in 10 people): fever greater than or equal to 100.4ºF (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), diarrhoea, headache.

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

Uncommon (may happen in up to 1 in 100 people): high fever, 104ºF (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. Itchy rash.

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:

- Enlarged lymph nodes;
- 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).

The vaccine that you/ your child will get in this study contains a substance called an "adjuvant." This substance may improve the immune response to the vaccine. People who have received vaccines that contain an adjuvant have very rarely (up to 1 in 10 000 people) developed illnesses called "autoimmune diseases", which can sometimes be serious and lifelong. Autoimmune diseases may develop when immune cells that normally protect you/ your child from illness, attack your/ your child's own organs instead. These illnesses have also developed in people who have not received these vaccines. GSK continues to monitor autoimmune diseases closely.

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What about pregnancy and breastfeeding?

The effects of the vaccine on an unborn child or a newborn baby are not well known. Therefore, you/your daughter cannot take part in this study if you/your daughter are/is pregnant, wish to become pregnant or if you are/your daughter is breastfeeding.

- If you choose to take part/let your daughter take part in this research study, you/she must use at least one of the acceptable methods of birth control during this research study (so that you do/she does not become pregnant). The study doctor will discuss the options with you, as described below.
- You / your daughter will have a urine pregnancy test before you/ she can receive any study vaccination.
- If you/ your daughter get pregnant during the study, tell the study doctor immediately. You/ your daughter will not receive any more vaccine, but you/ your daughter may remain in the study for follow-up. A separate Pregnant Participant ICF will be provided if you/your child become(s) pregnant which will allow the study doctor to follow-up with you soon after your estimated delivery date to check the outcome of the pregnancy and the health of your/ your child's new-born.

Are there other vaccines available?

If you/your child received vaccines against meningococcus B germ during infancy, no approved vaccines is available as booster dose.

If you/your child never received vaccines against meningococcus B germ, you can choose another alternative vaccine such as Trumenba, also approved in the UK.

The important possible benefits is vaccine works by helping the body to make antibodies which protect you or your child against disease caused by meningococcus B germ.

The important possible risks are reactions to needle injection and the side effects of the Trumenba:

Reactions to needle injection: Fainting, feeling faint, or other stress-related reactions to any needle injection;

Possible Side effects of Trumenba:

Very common (may affect more than 1 in 10 people)

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- Redness, swelling and pain at injection site
- Headache
- Diarrhoea
- Nausea (feeling the need to vomit)
- Muscle pain
- Joint pain
- Chills
- Fatigue (feeling overly tired and exhausted)

Common (may affect up to 1 in 10 people)

- Vomiting
- Fever ≥38 °C

Not known (frequency cannot be estimated from the available data)

- Allergic reactions

You can talk with your family doctor about your options before you/ your child decide to join the study. The study doctor can advise you if you need more information.

What will happen to your/ your child's samples?

As part of the study, your /your child's blood samples will be taken. Your/your child samples will be given a unique code number. The code number will not identify you/your child directly and will not be linked to any data that may directly identify you/ your child (e.g., name, contact details, date of birth). Anyone who works with your/your child's samples will hold the coded information and results securely and in confidence.

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

For this study, your/your child's 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/ your child live.

GlaxoSmithKline Vaccines; Biospecimen Reception-B7,
Rue de L'institut, 89; Rixensart, B-1330,
Belgium

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your/ your child's samples are stored in,

Q Squared Solutions Limited
The Alba Campus (Rosebank)
Livingston
West Lothian EH54 7EG
Scotland, United Kingdom

Your/your child's samples will be tested to look at how your/your child's body reacts to the vaccine(s) .

Learn more about how your/your child's samples will be used in Annex 1.

Your/your child's samples may be kept for a maximum of 20 years as per GSK standard retention period from the end of the entire study after which time your/ your child's samples will be destroyed.

You/ Your child when old enough, may request destruction of your/ their samples (left over at the time of the request) at any time by telling the study doctor.

You will be asked if you want to allow further research on the samples you/ your child provide.

What will happen to your/your child's personal information (data)?

The study doctor and other study staff will collect data that can identify you/your child.

This may include:

- Your/your child's name, address, telephone number. .
- Your/your child's age date of birth and gender.
- Your/your child's ethnic and racial background.
- Lifestyle information; health and medical history.
- Your/ your child's study treatments and response to study treatments.
- Data extracted from testing your/ your child's biological samples.

All people are not the same. We know it is very important to understand how the study vaccine works in different people. We also need to understand how differences between people can affect the study vaccine. GSK collects information on the race, ethnic

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background, gender, and age of every person who joins our studies to help us reach these goals. GSK protects your/ your child's personal information. To learn how it is protected, see "Your/your child's Coded Data," below.

Figure 2 What happens to your/ your child's data

At Study Site		**Personally identifiable information:** These data are collected by the study staff to identify and contact you/your child. They are stored in the study medical records at the study site. GSK staff (e.g., study monitors), and others may check the study records, but they are never sent to GSK. Example: name, address, e-mail, phone number.
At GSK		**Coding of data:** All your/your child's data that will be sent to GSK will be coded. This means that GSK will not be able to link the data to you/your child. The code list is kept secure and confidentiality by the study site. If needed, GSK can ask the study doctor to make the link with you/your child. Examples: symptoms after vaccination, results from the study, etc.
At GSK and beyond		**Anonymisation of data:** When the code list is destroyed, your/your child's data is 'anonymised.' Once your/your child's data are anonymised, they can no longer be linked to you/your child by the study staff or GSK. All personal identifiers would be completely removed.

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Who has access to your/ your child's personal information?

All your/your child's personal information collected for this study will be stored in the study medical records and used by study staff at the study site.

GSK staff, people working on behalf of GSK, 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, people acting on behalf of GSK may view your/your child's data in person at the study location or by a video/audio call or securely sharing documents to a computer system without transferring the file or making a copy of it. Appropriate measures will be taken to protect your/ your child's personal information. No personal information used for study monitoring will be retained by GSK staff or others acting on behalf of GSK.

Regulatory agencies, such as the US Food and Drug Administration (FDA), European Medicine Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA) or others, review and approve new medicines. These agencies may also be granted direct access to your/ your child's information. This is so they can verify clinical study procedures and/or data.

Copies of your/your child's medical records may be sent to trusted third parties working with GSK for the purpose of independent review and adjudication by expert committee or for evaluation. They help GSK understand the study data. Any information that could be used to identify you/ your child is removed from the document(s) before they are taken from the study site. Only your/ your child's assigned study participant code number is included with these documents. Information that is not needed to understand study data will also be removed from these documents.

Your/ your child's coded data

During the study, a copy of your/ your child's personal information will be made. All data that may directly identify you (e.g., your/ your child's name, contact details, date of birth) will be removed from this copy and the new dataset will be given a numbered code (such as 123456). This is known as your/ your child's 'Coded data.'

Once it is coded, linking it to you/ your child is only possible through a code list. The code list is kept secure and confidential by the study site and is not shared with GSK or others. Personal data that directly identifies you/ your child will not leave the study site or be sent to GSK.

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Your/ your child's coded data will be shared with:

- GSK and/or trusted third parties working on behalf of GSK and/or institutions working with GSK who are contractually bound to protect your/ your child's coded data. This is for the purposes of this study, and other purposes described in Annex 1 or further research (if you have consented to this). GSK will protect your/ your child's coded data and will only share it as described in this consent form.
- Health agencies, such as the US Food and Drug Administration (FDA), European Medicine Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA) or others, who review and approve new medicines. These agencies will be granted direct access to your/ your child's information. This is so they can verify clinical study procedures and/or data.

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

Anonymised data

GSK may "anonymise" a copy of your/ your child's coded personal information. This means all personal identifiers will have been completely removed, and your/ your child's information will be further processed so that it can no longer be linked to you/ your child.

GSK, other scientists, and organisations use anonymised 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.

The results of these further research studies will not be shared with you/ your child but may be published by the researchers.

To learn more about how your/ your child's data will be used in Annex 1

Further Use of Coded Samples and Data

If you agree to the use of your/ your child's coded samples and data for further research related to this study, this will be used by GSK and others, for example universities or other companies, to:

- Learn more about the vaccine.
- Learn more about the study disease and related conditions, including to develop new and related treatments.

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If you agree to the use of your/ your child's coded samples and data for further research that is NOT related to this study, this will be used by GSK and others, for example universities or other companies, to:

- Study other diseases and treatments.
- Develop new research methods and tests.

You may withdraw your consent for further use of your/ your child's coded samples and data at any time.

Except as otherwise explained above, the results of these further research studies will not be shared with you, but may be published by researchers.

You/ your child can still join the study if you disagree to the further use of coded samples and data. You will be asked to indicate your choice on the signature page.

Communication of information related to this study

The study doctor will share any new information that might change your/ your child's choice to stay in the study and discuss with you as soon as possible.

When the study is ongoing, we may discover information that is important to your/ your child's health or welfare. Findings needing medical care will be shared with your/ your child's study doctor who then will inform your/ your child's doctor for taking adequate actions in line with the local laws.

When the study is completed at all the study sites, the study results will be shared with the study doctor, and you/ your child can ask the study doctor to explain the study results to you. You may ask the study doctor for your/ your child's individual results.

A description of this study will be available on public registries like http://www.clinicaltrials.gov, and EU CTIS portal, this portal will also publish study results. When posted on other public clinical trial registries, the study will be also posted on GSK Study Register http://www.gsk-clinicalstudyregister.com,. It may also appear in clinical trial registries in countries where the study is conducted.

When the results are available, a summary of the results will be posted on public registries, as described above. Results for the study are generally available within a year of collection of key study data. You can search this website at any time.

GSK will develop an easy to read summary of the study results when the results are available. This result summary will be made available

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on https://www.trialsummaries.com, and the GSK study register (www.gsk-studyregister.com/en/), and on EU CTIS portal.

You may sign up on www.trialsummaries.com for an email notification when the summary becomes available.

None of these postings to registries or websites will include any data that can identify you/ your child.

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. If you agree, GSK will use your/ your child's coded data and samples for further research and may further profit from the results of further research. You/ your child will not be paid any part of this.

What happens if you/ your child want to leave the study?

You/your child can leave the study at any time without giving any reason. Your choice will not change the quality of care you/ your child would usually receive outside of this study.

Tell the study doctor if you/ your child's are/is considering leaving the study. The study doctor will discuss with you the best way to do this.

If you/ your child leave the study, all the coded data and samples collected while you your child were in the study will remain as part of the study and will be used as described in this form. You/ your child have the option to request the destruction of your/ your child's unused samples where practical and possible by speaking to your/ your child's study doctor.

The study doctor may find out information about your/ your child's health after you/ your child have/ has left the study. If this information relates to the safety of the vaccine you/ your child received during the study, the study doctor will send it to GSK.

If you previously agreed to the further use of your/ your child's coded data and samples for further research, GSK will keep and use these as described in this form. You can withdraw your consent for this at any time.

Can you/ your child be asked to leave the study?

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You/ Your child may be asked to leave the study if:

- Test results show that this study is not suitable for you/ your child.
- You/ your child do not follow the study instructions.
- The study doctor thinks it is best for you to stop taking part in the study, for example if you develop specific health problems.
- The entire study needs to be stopped for everyone.
- If you/your daughter gets pregnant.

If this happens, your study doctor will explain the reason to you and will arrange appropriate care for you.

What happens if you/ your child are/ is harmed or injured during this study?

- If it is an emergency, call the emergency number for help or go to hospital A&E.
- For other medical problems related to the study drug/vaccine or a procedure done to you/your child as part of this study that is not an emergency, contact the study doctor immediately. The study doctor will take care of you/your child or will contact another doctor, if needed.
- We will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). We will pay compensation where the injury probably resulted from:
  - A Vaccine being tested or administered as part of the trial protocol
  - Any test or procedure you your child received as part of the trial. Any payment would be without legal commitment.

  (Please ask if you wish for more information on this)
- We would not be bound by these guidelines to pay compensation where:
  - The injury resulted from a drug or procedure outside the trial protocol
  - The protocol was not followed.

  Or
  where the study doctor has acted negligently.
- The Sponsor has taken out an insurance policy to cover compensation for any personal injury resulting from you/ your child taking the study drug, provided such personal injury is not due to fault or negligence of the study doctor or his team.

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- If you have private medical insurance, please check with your insurance company that taking part in this study will not affect your policy.
- Signing this document will not affect your right to take legal action if you believe you were injured because you were in this study or any other legal rights you have.

Will you/ your child be paid for taking part in the study?

- At each visit we will reimburse you/ your child for the cost of travelling to your/ your child's study visits (including parking). For visits lasting over 3 hours you/ your child will be reimbursed for refreshments. If you/ your child require a companion due to your/ your child's medical condition, we will also reimburse their travel expenses and refreshments.

Do you/ your child have to pay anything to take part in the study?

GSK is responsible for covering the cost to conduct this trial. You do not have to pay to take part in this study. You/ your child will get the study vaccine and all the study tests and procedures at no cost.

Who has reviewed this study?

All research studies are reviewed by an independent group of people, called a research ethics committee to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favourable opinion by XXX Research Ethics Committee.

It has also been reviewed and approved by the UK regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA).'

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Whom should you/ your child contact if you have questions?

If you need further information, but also if you have problems or concerns, you can contact

Study Doctor Name: _____

Study Doctor Phone: _____

Study Nurse Name: _____

Study Nurse Phone: _____

(where applicable):

24 hours Emergency Contact Name: _____

24 hours Emergency Contact Phone: _____

If you have any questions relating to your rights as a study participant, you can contact the patient rights ombudsman of your institution on this telephone number .

If you would like to raise a complaint, you may contact <site to insert contact details> or the local Patient Advice and Liaison Service (PALS) <site to insert>.

Name: _____

Phone: _____

Email: _____

Address: _____

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Annex 1 Additional Information about how your/your child's coded samples and data may be used

Why will your/your child's coded samples and data be collected?

GSK will use your/your child's coded samples and data to:

- Carry out this study and meet the study purpose.
- Understand results of this study.
- Bring the vaccine to market and support reimbursement.
- Satisfy regulatory requirements.
- Develop diagnostic tests to support use of the vaccine.
- Ensure the quality of the tests used for the vaccine(s) or disease(s) is maintained over time.
- Develop and improve tests related to the vaccine(s or disease(s).
- Design additional studies relating to the /vaccine, study disease and related conditions.
- Your/your child's coded samples and data may be used along with samples and/or data from other studies and sources.
- Test and improve GSK computer systems that support clinical study processes.
- Publish results of the study. If we do this, your/your child's name will not appear in any publication.
- Foster clinical trial diversity in ethnic groups.

Some of your/ your child's data may be processed within the European Union. The European Union General Data Protection Regulation (GDPR) states that GSK and the research site should state the reasons for processing your/ your child's personal information. GSK's bases are as follows:

GSK uses study information and ethnic and racial information for the purposes of conducting the study in the company's legitimate interests of scientific research and for reasons of substantial public interest. We use this information to better understand how the study vaccine works in different people and how those differences affect the study vaccine.

- GSK uses safety information to comply with its legal obligations that are necessary for reasons of public interest in the area of public health.

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- If you agree to further use of your/your child's personal information, GSK will use this information based on your consent. You have the right to withdraw this consent at any time.

How is your/your child's personal information protected?

All appropriate measures will be taken to protect your/ your child's personal information. These measures will comply with data protection and privacy laws that apply.

Your/ your child's coded data may be transferred to countries outside the UK. Data protection and privacy laws may not be as strong in these countries as the laws in the UK. However, when data are transferred, GSK makes sure that appropriate safeguards are used to protect your data.

More information about the safeguards used is found at:

- https://ec.europa.eu/info/index_en (use the site search function to search for "model contracts for the transfer of personal data"); and

- https://www.gsk.com/en-gb/about-us/codes-and-standards/binding-corporate-rules/ (GSK's Binding corporate rules)

What are your/ your child's rights to access your/ your child's data?

You have/your child has certain rights we need to make you aware of. In some circumstances, the rights available to you/your child may be limited, for example by legal requirements to maintain a copy of study records or to protect the scientific integrity of a study.

At any time, you may ask the study doctor:

- To learn more about what is done with your/your child's data.
- For a copy of your/your child's data.
- To correct information you think is inaccurate or incomplete.
- To request deletion of your/your child's data.
- To transfer your/your child's data to a third party (such as your/your child's personal doctor) for re-use.

You may also:

- object to what is done to your/your child's data.
- Claim compensation for damages caused due to unlawful use of your/your child's data, through the courts.

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- To lodge a complaint with the Information Commissioner's Office (ICO) where you consider that because of the processing of your/your child's personal information your privacy rights are violated.

However, depending on when you request it, these rights to access, change or move your information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

You can make these requests by contacting the study doctor, or GSK's data privacy officer using the contact details below. Please first contact the study doctor to retain your anonymity.

If you are not happy with their response or believe they are processing your/ your child's data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (https://ico.org.uk/make-a-complaint/ or 0303 123 1113)

Claim compensation for damages caused due to unlawful use of your data, through the courts.

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

Your/ your child's coded data will be used only for as long as it is needed for the study. It may be kept for longer, where required by law.

Your/ Your child's coded data may also be kept for use for further research as described in this form, unless you have chosen not to consent for further research or you withdraw your consent.

GSK must keep the coded data from research studies for at least 30 years.

Who will collect and process your/your child's data?

A data controller collects and processes data. It determines why and how it is processed. GlaxoSmithKline is the data controller for this study.

You can contact the GSK's Data Privacy Officer at EU.DPO@gsk.com.To retain your/ your child's anonymity, please contact your study investigator (see details above) as a first instance.

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Consent form

Study title: A Phase 3 study to assess the immune response and safety of rMenB+OMV NZ in primed healthy participants (10 to 20 years old)	
Study identification:	220030
Abbreviated title	MENB REC 2ND GEN-096 BST:002,055,058
EU CT number	2024-519549-31
Name of company sponsoring the study:	**GlaxoSmithKline Biologicals SA or GlaxoSmithKline Research**
Study participant ID	**[Insert participant ID number here after consent is obtained]**
Name of study doctor:	**[Insert doctor's name]**
Address of research site:	**[Insert name and site address]**
Phone number:	**[Insert site phone number]**

I understand the purpose of this study and the content of this form. I am satisfied with the answers to my questions and had enough time to decide whether I want to take part in the study. I am aware that I can change my mind and leave the study at any time without giving a reason.

Please note- All boxes below need to be initialled in order for the participant to be enrolled into the study.

By signing this form:

	Participant Initials
1. I agree to take part in the study/ I agree for my child to take part in the study.	

2. I agree that my/ my child's samples and data can be used as described in this form.	
3.I have been given names of study staff who I can call if I have any questions about the study.	
4.I understood that the study doctor can ask me/ my child to stop taking part in the study at any time and will tell me the reason why.	
5.I acknowledge that I/ my child cannot be in another research study while I am taking part in this study.	
6.I agree that study doctor may inform my/ my child's GP that I'm/ my child is taking part in a study.	
7.It has been explained to me that I have not waived my/ my child's legal rights by signing this document.	
8. I will receive a copy of this signed document to take with me.	
9.I will tell the study doctor straight away if I get/ my child is pregnant and understand that I/ my child will no longer be able to take part in this study.	
10. I understand that relevant sections of my/ my child's medical notes and data collected during the study, may be looked at by individuals from IQVIA, a CRO assigned by the sponsor, from regulatory authorities or from the Oxford Vaccine Group, where it is relevant to me/ my child's taking part in this research. I give permission for these individuals to have access to my/ my child's records."	

Please indicate if your/ your child's coded samples and data can be used by GSK and others, such as universities, or other companies, for further research <u>related</u> to this study as described in this form:

☐ Yes, I agree ☐ No, I do not agree

Please indicate if your/ your child's coded samples and data can be used by GSK and others, such as universities or other companies, for further research NOT related to this study as described in this form:

☐ Yes, I agree ☐ No, I do not agree

You may withdraw your consent for further use of your/ your child's coded samples and data at any time.

Person agreeing to take part (Study participant)

First and Last Name:

Signature: Date:

Study participant's parent or guardian(s)

First and Last Name:

Name of study participant:

Relationship with study participant:

Signature:

Person conducting consent

By signing below, I show that:

- I have explained the study to the potential study participant and what will happen to the potential study participant's data and samples collected during the study.
- I have given the potential study participant the chance to ask questions and I have answered them to the potential study participant's satisfaction.
- I have given the potential study participant enough time to think and decide whether or not the potential study participant wants to take part in the study.
- I explained that the potential study participant may talk with others before making a decision.
- A copy of this Informed Consent Form has been provided to the study participant.

First and Last Name:

Signature: Date:

When completed: provide 1 copy for participant; 1 for researcher site file; 1 to be kept in medical notes.