OXFORD VACCINE GROUP

Investigating a new Vaccine Against Meningitis B in OXford

VAMBOX

Study Information Booklet

Serum Standard - Groups 6, 7 and 8

You are invited to take part in a study to test a new vaccine against Meningitis B, which is an important cause of meningitis and septicaemia in children and adolescents. The study is being run by the Oxford Vaccine Group, which is part of the University of Oxford.

Before you decide whether to take part, it is important for you to understand what the study is about and what participation would involve. Please take time to read the information carefully, and discuss with others if you wish. If anything is unclear or you would like further information please contact the study team.

Thank you for taking the time to consider taking part in this study.

Contact Details

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Centre for Clinical Vaccinology and Tropical Medicine (CCVTM)
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Oxford OX3 7LE
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Glossary

Neisseria meningitidis – A type of bacteria that is an important cause of meningitis and septicaemia in the UK. Exists as several subtypes.

Meningitis B – Meningitis caused by the *Neisseria meningitidis* type B

Bexsero® – The current available vaccine against Meningitis B which is given to babies routinely in the UK.

Trumenba® - A licenced vaccine against Meningococcal B disease.

Serum Standard - The component of blood that is neither a blood cell nor a clotting factor; includes antibodies, antigens, hormones, and any foreign substances (e.g. drugs and microorganisms). Serum is used in laboratory testing to enable standardisation of results across laboratories worldwide.

Who is the Oxford Vaccine Group?

The Oxford Vaccine Group, which is part of the **University of Oxford**, is an independent research team of doctors, nurses and play assistants. We carry out research studies of new and improved vaccines for babies, young children, teenagers and adults, and teach doctors and nurses about immunisations. In the past 5 years alone, over 7,000 participants in the Thames Valley area have taken part in our research studies.

Why have I been invited to take part?

We are inviting healthy adults aged 18 to 50 years old to take part in this study. We use various ways to contact potential volunteers, including the Electoral Roll and the National Health Applications and Infrastructure Services (NHAIS) who holds the central NHS patient database (Open Exeter). This database identifies all persons within the local area who are in the appropriate age range.

What is Meningitis B?

Neisseria meningitidis is a type of bacteria that can cause meningitis (infection of the lining of the brain) and septicaemia (blood poisoning), particularly in infants, children and adolescents. There are several different types of these bacteria which are often labelled with a letter. *Neisseria meningitidis B* is one of these types and the disease it causes is called Meningitis B.

In 2015/2016 in the UK there were 805 documented cases of invasive meningococcal disease (that is, disease caused by *Neisseria meningitidis;* either meningitis or septicaemia), with 43 deaths. *Neisseria meningitidis B*, or Meningitis B, accounted for 55% of the total number of cases, with most of the disease in infants and younger children.

What is the purpose of this study?

In this study we are testing a new vaccine against *Neisseria meningitidis B.* There are two current vaccines against Meningitis B called Bexsero® and Trumenba®. However, these vaccines commonly cause side effects (fever and pain); require two to three injections to establish immunity; and are reasonably expensive (RRP £75 per dose). The Oxford Vaccine Group is therefore proposing a new vaccine, which may produce a better immune response, be cheaper and require fewer doses. This study is being conducted to evaluate the safety of the new vaccine and how well it stimulates the immune system against meningitis B in comparison to the current vaccines. We are also aiming to recruit

participants into a new part of the VAMBOX study, called serum standard. The purpose of a serum standard is to create a supply of antibodies directed against Meningitis B by using serum (the portion of the blood that does not contain any cells) from participants vaccinated with either Bexsero® or Trumenba®. Vaccination causes an immune response, which includes the production of antibodies. Producing a reference serum helps us to determine how well the vaccine is working in those who have been immunised. It helps us determine a cut-off value above which we can say that a vaccine is protective (otherwise known as a "correlate of protection"). It also helps us standardise results across laboratories worldwide.

We are aiming to recruit a total of 79 to 90 participants to take part in the VAMBOX study, 40 of which will take part in the serum standard. We are inviting **healthy adults aged 18 to 50 years old** to take part in this study.

In summary, what would happen if I decide to take part in the study?

- We would ring you to check that it is appropriate to include you in the research.
- You would then attend a screening visit at the CCVTM where you would have a blood test and urine test (and a pregnancy test for women). These are to assess your eligibility for the study.
- Following satisfactory screening results you would be enrolled into the study.
- You would be vaccinated with Bexsero® or Trumenba®.
- If you were in Groups 6 or 8 you would fill in an eDiary
- We would continue to see you for the occasional clinic visit up to 13 months after the start of the study.

What vaccines are given in the study?

If you join the serum standard groups in this study, you would be allocated to receive two doses of Bexsero® or two doses of Trumenba® - both of which are **licensed vaccines** against Meningococcal B disease.

What are the different study groups?

The study groups discussed in this study information booklet for Serum Standard are Groups 6, 7 and 8. Existing Group 6 participants who have already enrolled in the main VAMBOX study may choose to join serum standard by signing the Serum Standard Informed Consent Form. More information on Groups 1 to 6 can be found in the main study information booklet. A synopsis of each of the groups can be found below for information only.

Group 1 - Low dose arm – This group will consist of 3-6 individuals who will receive a single dose of ChAdOx1 MenB.1

Group 2 - High dose arm –. This group will consist of 10 participants assigned to receive a single dose of the higher dose of ChAdOx1 MenB.1.

Group 3 - High dose plus booster arm – this group will consist of 8 participants who will receive the high dose of ChAdOx1 MenB.1, with a repeat booster dose at 6 months

Group 4 - Bexsero® with high dose ChAdOx1 MenB.1 booster arm – this group will consist of 8 participants who will receive a dose of Bexsero® at Day 0 with a booster high dose of ChAdOx1 MenB.1 at 6 months.

Group 5 - Bexsero® Control arm – This group will consist of 10 individuals who will receive two doses of Bexsero® at Day 0 and Day 28 as per adult licensing. This group will act as a control to groups 1 and 2.

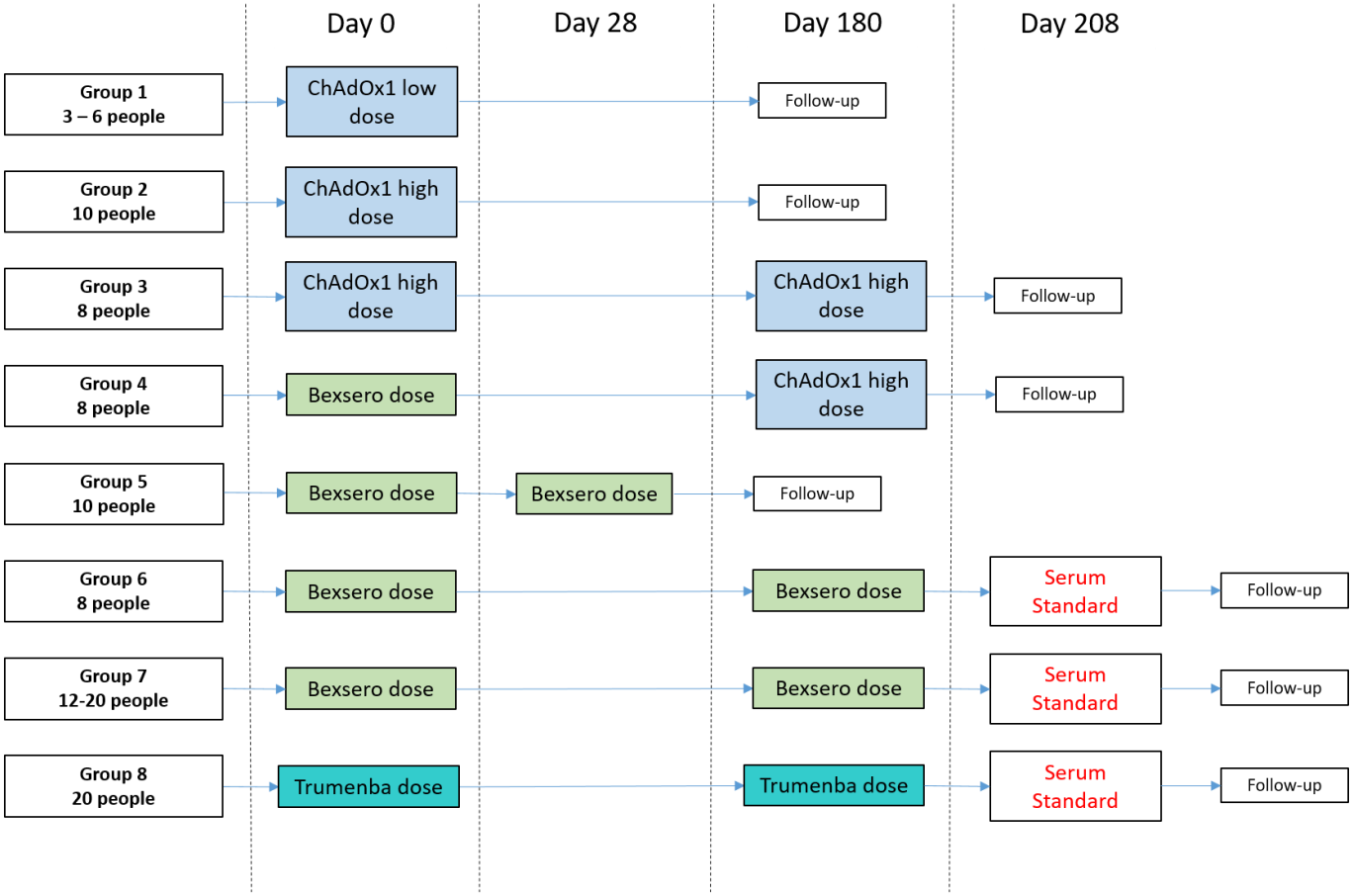
Group 6 - Bexsero® 6 month boost control arm – This group consists of 8 individuals who will receive Bexsero® doses at Day 0 and 6 months. This group will act as a control for groups 3 and 4. If participants choose to be a part of the serum standard, they would have a large blood donation at 7 months.

Group 7 (Bexsero® 6 month boost serum standard arm) – Single dose of Bexsero® vaccine followed by a second booster dose of Bexsero® vaccine at 6 months. Serum standard donation at 7 months.

Group 8 (Trumenba® 6 month boost serum standard arm) – Single dose of Trumenba® vaccine followed by a second booster dose of Trumenba® at 6 months. Serum standard donation at 7 months.

If enrolled, you will be allocated to **Group 6, 7** or **8** as described above. You will be told which group you are allocated to. See **Figure 1** and **Figure 2** for an overview of how the trial is organised.

Figure 1: Overview of the trial.



Who can take part in the study?

We are keen to recruit **healthy volunteers** who are:

- Willing and able to take part and able to attend all visits
- Aged between 18 and 50 years old, inclusive
- Willing to allow us to communicate with their GP to notify them of enrolment and to verify the medical history, if required
- (**Females**) Willing to use effective contraception from 1 month prior to starting and for 3 months after the last vaccine

You would not be able to take part if you:

- Have significant medical problems
- Have previously had meningitis and/or septicaemia caused by *Neisseria meningitidis*
- Have received:
    - a **Meningococcal ACWY** vaccine in the last 10 years
    - a **Meningococcal C** vaccine in the last 10 years
    - ANY vaccine or plan on receiving ANY vaccine within 30 days of vaccination during the study
- Have had a serious allergic reaction to vaccines
- Have or are planning on donating blood within 3 months (male) or 4 months (female) of the start of the trial
- (Females only) Are pregnant or breastfeeding

What are the benefits of taking part?

Information from this study may help doctors learn more about this study meningitis B vaccine. This information may help us to make a vaccine that can protect babies, children and adults against meningitis B. The serum standards may enable standardisation of meningococcal B antibody testing across laboratories, to better evaluate meningitis B vaccines more broadly.

What side effects or risks can I expect from this study?

Like all vaccines, the meningitis B vaccines, Bexsero® and Trumenba®, can cause side effects, although not everybody gets them. If there are side effects, they usually happen in the first 3 days after vaccination and they do not last for a long time.

The most common side effects of these vaccines are (seen in more than 1 out of 10 vaccinated people):

- Local side effects at the injection site: pain, swelling, hardening and redness.
- General side effects: headache, nausea (feeling sick), generally feeling unwell, muscle pain, joint pain, and chills.

As with all injected vaccines, unexpected, severe allergic reactions may very rarely occur. An allergic reaction, sometimes referred to as anaphylaxis, can be recognised by itchy skin rash, swelling of the face, difficulties in breathing and swallowing or by a sudden drop in blood pressure. If such reactions occur, they usually start very soon after vaccination. That is why it is important that you stay at the

study site for at least 15 minutes after vaccination, where study nurses and doctors have the medical equipment and training in order to manage these types of allergic reactions.

We will observe everyone in the study for any side effects, particularly in the first seven days after receiving a vaccine with an eDiary that you will fill in (see Table 2). Side effects may be mild to moderate. Most effects will stop shortly after receiving the vaccine. In rare cases, side effects can be serious or prolonged, although no serious concerns have been raised in human trials of either of these vaccines. It is important to notify the study team if you are at all worried about your symptoms.

You may take medicines after you've received a vaccination to help lessen side effects; for example, if you have a fever you could take paracetamol to help treat it. Any medication you have taken during the study should be recorded in your eDiary. If you have a severe reaction, we may give you medicines to assist you.

This study also involves several blood tests. Taking blood samples may sometimes result in bruising to the area and some people can feel faint. If you were feeling faint, our staff would ask you to stay at the clinic until you felt well again. The participants in the serum standard will have extra blood tests taken at Visit 12 (between 200ml and 315ml). To do this we will insert a cannula (a thin, flexible tube) into your arm.

It is sensible to ensure you have drunk plenty of water/juice and had something to eat before giving blood to help your body adjust quickly and avoid feeling faint. You would be welcome to stay with us until you feel ready to go home.

It is a rare occurrence, but in the unlikely event we noticed anything unusual and potentially of medical significance about your blood then we would always contact you to discuss the information and help with what would be a sensible next step.

What safety measures are in place during the study?

As both Bexsero® and Trumenba® vaccines are licensed, we do not anticipate any causes for concern. The safety outcomes of the study participants will be monitored by assessment of symptoms at visits and through the eDiary. We will also check your haemoglobin if you were donating the larger blood volume at the Visit 12. This is to ensure it is safe for you to give this larger volume of blood. You will have access to a study doctor 24 hours a day until the end of the study. It is very important that you stay closely in touch with the study team and let us know as soon as possible if you are concerned about any of your symptoms.

Pregnancy

You should not take part in this study if you are pregnant or breastfeeding. Female participants must be willing to use effective contraception from one month prior to starting and for 3 months after the last vaccine to avoid pregnancy. If you get pregnant during this study, inform the study staff promptly. You would not receive any more vaccine but may remain in the study for follow-up. You may be asked questions later about the pregnancy and the baby.

What are the study procedures?

You would be expected to do the following during the study:

- You would need to come to our study clinic at the Churchill Hospital for 4 to 14 visits over one year.
- You would receive two vaccinations as an injection in your upper arm.
- You would get the first vaccination at the first study visit post-screening and an additional vaccine at six months.
- After each vaccination you would need to stay at the clinic for 15 minutes so that you can be observed.
- You would be asked to tell the study staff about other hospital or GP visits, unscheduled healthcare tests (lab tests, X-rays etc.) or procedures (e.g. Endoscopies, surgery etc.)
- For further information please see **Tables 1 to 3.**

Table 1: Summary of visits for Group 6

Visit Number	Screening (V0)	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13
Indicative Study Day		1	2	7	14	28	56	84 (12w)	180 (26w)	V8 + 1 day	V8 + 7 days	V8 + 14 days	208 (30w)	365 (52w)
Medical history	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Urine pregnancy test	x	x							x					
Blood sample	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Serum standard													x	
Vaccination		**x**							**x**					
e-Diary review		x	x	x	x	x			x	x	x	x	x	

Table 2: Summary of visits for Group 7

Visit Number	Screening (V0)	V1	V8	V12
Indicative Study Day		1	180 (26w)	208 (30w)
Medical history	x	x	x	x
Urine pregnancy test	x	x	x	
Blood sample	x	x	x	x
Serum standard				x
Vaccination		x	x	

Table 3: Summary of visits for Group 8

Visit Number	Screening (V0)	V1	V2	V3	V5*	V8	V9	V10	V12	V13*
Indicative Study Day		1	2	7	28	180 (6m)	V8 + 1d	V8 + 7d	208	365
Medical history	x	x	x	x	x*	x	x	x	x	x*
Urine pregnancy test	x	x				x				
Blood sample	x	x	x	x	x*	x	x	x	x	x*
Serum standard									x	
Vaccination		x				x				
e-Diary review		x	x	x		x	x	x		

*10 individuals as a subset of group 8

If you express an interest in taking part, a member of the Oxford Vaccine Group will contact you by telephone to discuss the study and answer any questions you may have. Following this, if you are interested and seem suitable for the study then we would arrange for you to come to our clinic for a screening visit.

What happens at my Screening Visit?

The purpose of screening is to assess whether you are able to participate in the study. The screening visit takes about 90 minutes. We would sit with you and go through the study in detail. This visit would provide an opportunity for you to ask any further questions you might have about the study and what is involved. You would be allowed as much time as you feel necessary before making any decision on whether to take part.

If you wish to proceed, we would ask you to sign an **informed consent form**. Only once this is signed would we then start any study procedures.

We would ask you questions about your health and take a blood sample to ensure you are healthy. All groups would also have a physical examination, including an ECG ('heart tracing') and a urine sample. You would have a blood test to screen for HIV, hepatitis B and C, to check your general health and your haemoglobin level. For all females, we would perform a pregnancy test on your urine sample.

During your screening you would be asked to provide your National Insurance number (or passport number if you do not have a National Insurance number). This would be entered on to a national database which helps prevent volunteers from taking part in too many clinical trials. The Trial Over-volunteering Prevention Service (TOPS) database is to ensure safety of all our participants in this study and therefore if you are unwilling to have your information submitted on TOPS you would not be able to take part in our study. More information can be found at http://www.hra.nhs.uk/about-the-hra/our-committees/the-over-volunteering-prevention-system/.

Once the study team have confirmed your suitability for the study, we would inform you and arrange a date for your first visit. Your participation in this study is at the researchers' discretion.

If you have already been consented to take part in Group 6 or are currently enrolled, you would not need to undergo further screening. However, we would ask you to sign a new informed consent form for the serum standard portion of the study.

Is coming to screening a commitment to taking part?

No. It is an opportunity to meet with the study staff and ask questions. You do not need to make a decision there and then.

What samples are taken during the study?

Depending on which group you are in, you would have between 2 and 14 blood tests. The amount each time would be between 6 mL (about 1 ½ teaspoons) and 315 mL (about two thirds of a blood donation) depending on the tests that will be done. Some of these blood tests will also be taken for genetic analysis to see whether a particular genetic makeup affects your response to the vaccine. For this reason it is necessary for us to record your ethnicity as this influences how we interpret your genetic tests.

The total amount of blood taken during the whole study (1 year) would be up to 1307 mL, which at a maximum would be about equal to two "blood donations" to the UK Blood Transfusion Service. Your body would replace this blood after about three months. For the larger blood tests (i.e. 315 mL) the nurse or doctor will insert a cannula (tiny plastic tube) into your hand or arm.

There might be a case in which your blood needs to be retested or a urine sample taken to confirm test results. This might happen at your next visit or at an unscheduled visit that you would need to come to the clinic for. At this visit the study staff would take a sample of your blood (10 mL, 2 teaspoons) and collect a urine sample, as needed.

What will happen to the samples I give?

Your sample will be assigned a code and your data will also be identified only by this number. The material given to researchers will not have information that identifies you. The blood and urine samples collected during this study would be analysed in the Oxford University Hospitals, University of Oxford research laboratories, as well as the National Institute for Biological Standards and Control (NIBSC). We would also send some samples to other researchers working with us on this research project, including researchers outside the European Union. These samples would be anonymised.

Individual and pooled serum will be processed by our collaborators at NIBSC and will form an international serum standard. This means that it will be used by laboratories across the world as a "control" in laboratory tests to measure antibodies directed against Meningitis B (specifically, antibodies against the proteins on the bacteria). Some sera may be used to further develop tests for measuring antibody levels.

Participants in groups 6 and 8 will be asked for a separate permission to store blood (including cells and DNA) samples, in a collection of samples called Biobank. Details of this will be provided in a separate booklet after you are enrolled into this study. You are free to say no to the Biobank and continue to take part in this study if you wish.

What if any of my test results were abnormal?

If abnormal results or undiagnosed conditions are found in the course of the study these would be discussed with you and, if you agreed, your GP would be informed of these results. We would not report them to anyone else without your permission. For example, a new diagnosis of high blood pressure might be made. Any newly diagnosed conditions would be looked after by your GP.

Diary

After each vaccination, we would ask you to complete an online eDiary, with a paper back up in case you were unable to access the internet. The first section will cover the first 7 days after vaccination and you will be asked to take your temperature, measure any injection site reactions (e.g. redness or swelling) with a ruler and record if you've had any symptoms or taken any medications. You will also be asked to fill in second section to record whether you've had any medications, symptoms or have been seen by your GP or any other health professional from day 7 and up to a month after each vaccination.

How am I reimbursed for my involvement in the study?

Study participants would be reimbursed for their time, travel and inconvenience of taking part in the study. The maximum reimbursement for any volunteer is who completes the whole study is £160 to £630 dependent on their study group. All participants will be reimbursed based on the following figures:

- Travel expenses: £15 per visit
- Inconvenience of blood tests: £10 per blood donation
- Time required for visit: £20 per visit

The sum reimbursed is on a pro rata basis, so, if for example, you choose to withdraw half way through the study we would calculate your reimbursement based on the visits you have attended and samples that have been obtained.

Payments are made directly by bank transfer in instalments during the study (after screening, V5 or V8, V12 and V13). For this reason we would require participants to provide their bank details at screening.

Bank details would be kept confidential. Personal information such as your name, bank details and national insurance number may be shared with the University finance team to process or verify your reimbursement payments. Financial auditors may also audit the records where this information is held. All confidential data will be stored according to the General Data Protection Regulation (GDPR).

You may also receive reimbursement for any unscheduled visits you attend (if you have symptoms from the vaccine and need to be assessed). You would be reimbursed £45 per unscheduled visit, up to a maximum of £135 (equivalent of 3 unscheduled visits). If you do not require any unscheduled visits, you will not be reimbursed for this amount.

Do I have to take part?

No. We are looking for volunteers. Should you volunteer and later change your mind (for whatever reason) it is your right to do so, and you would not need to provide an explanation to the study team or anyone else.

If you withdraw from the study, unless you state otherwise, any blood or tissue samples which have been collected whilst you have been in the study will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples are destroyed at any time during or after the study.

Whatever you choose it's important that you are happy with your decision and it is not the role of the study team to decide for you. We would help present the details of the study and answer all your questions so you could make an informed decision.

Would my taking part in this study be kept confidential?

Yes. All information that is collected about you during the course of the research would be coded with a study number and kept strictly confidential. Any information about you that leaves the clinic would have your name and address removed so that you could not be recognised, with the exception of letters sent to your own GP. In order to enrol into this study, you would be required to sign a form, documenting that you consent for us to contact your GP. This is to inform him/her that you would be entering the study, and to ensure there are no medical reasons that would prevent you from taking part in this study. No one else would be told that you are involved in the study. We would only notify your GP of the results from any medical tests we performed with your permission.

Your information would be stored on a secure server, and paper notes would be held by the Oxford Vaccine Group in a locked cabinet. Your data is retained in case we need to contact you regarding any

study related matters or if you wish to contact us regarding your participation in the study. We may also contact you to inform you of future related studies.

Responsible members of the University of Oxford and the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. In addition, the following groups may inspect the study records without violating your confidentiality:

- Monitors who check that the study is being conducted to a high standard, including the Data and Safety Monitoring Committee (DSMC), an independent panel of experts responsible for trial safety.
- The Clinical Trials and Research Governance Office (CTRG), University of Oxford, who are responsible for ensuring the appropriate conduct of the study on behalf of the research Sponsor (the University of Oxford).

Anonymised data and samples would be sent to other researchers working with us on this research project, including researchers outside the European Union and the study funders.

For serum standard, participants' samples will be fully anonymised and sent to the National Institute of Biological Standards and Control (NIBSC). These samples will only be identified by study code. NIBSC will not have access to your personal data and will not be able to identify you. Please also note that once your samples and data have been anonymised for making serum standards, they cannot be retrieved even in the event of withdrawal from the study.

General Data Protection Regulation (GDPR)

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly.
We will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. The only people in the University of Oxford who will have access to information that identifies you will be people who need to contact you to conduct the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.
The University of Oxford will keep identifiable information about you from this study for at least 5 years after the study has finished. We will securely store the anonymised research data and any research documents with personal information, such as consent forms, for at least 5 years after the end of the study. The need to store this information for longer in relation to licensing of the vaccine will be reviewed every 5 years.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to my data?

Once the study has been completed, all documents would be archived in a secure facility by Ardington Archives storage (Faringdon, Oxford). Files will be confidentially destroyed if storage is no longer required. For effective vaccines that may be licensed, secure storage of research data may be required for at least 15 years after the end of the study, subject to adjustments in clinical trials regulations. Your bank details will be stored for 7 years in line with University financial policy.

Professor Andrew J Pollard, or his successor, as Director of the Oxford Vaccine Group will have the responsibility for custody of the data. Further information about your rights with respect to your personal data is available at:

http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

What will happen at the end of the research study?

The results of the research will be published in a scientific medical journal; this can potentially take a few years. All OVG publications will appear on the OVG website and you will receive a letter containing these results. Your individual results would not be identifiable nor would you be identified in any report or publication. The results of the research will also potentially be used for future academic research within the Oxford Vaccine Group.

Once the last laboratory test is performed in the study, all non-serum standard samples will be destroyed, unless you have consented for them to be transferred to the Biobank. If your samples are going to the Biobank, a copy of your informed consent form (which contains your personal information), are stored with those samples.

Anonymised serum standard samples sent to NIBSC will be analysed and made into serum antibody standards. These biological materials will be stored at NIBSC and made available to the scientific community worldwide for commercial and non-commercial use as international reference standards.

What if there is a problem?

If you have private medical insurance, you are advised to contact your insurance company before participating in this trial. The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

Where can I get advice on whether to take part?

We are happy to answer any questions you might have and contacting us does not commit you to taking part in the study. For independent advice you can contact **INVOLVE** (www.invo.org.uk) which is a government funded national advisory group supporting those considering involvement in NHS, public health and social care research. Please feel free to discuss this study before deciding whether or not to participate.

What if I wish to complain?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Andrew Pollard, Director of the Oxford Vaccine Group, (Tel: 01865 611400, Email: info@ovg.ox.ac.uk) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 (6)16480 or the Head of CTRG, email ctrg@admin.ox.ac.uk.

At any time during the study you would be entirely free to change your mind about taking part, and to withdraw from the study. This would not affect your subsequent medical care in any way.

Who is funding the study?

Up to July 2018, the study will be funded by the Medical Research Council under a Developmental Pathway Funding Scheme award. After July 2018 the study will be funded by a National Institute for Health Research (Biomedical Research Centre grant). The serum standard study arm is funded by the National Institute for Biological Standards and Control (NIBSC).

Who has reviewed and approved this study?

This study has been reviewed and approved for conduct by South Central – Oxford A Research Ethics Committee (17/SC/0470), one of the national research ethics committees. This committee reviews research studies to protect the rights and wellbeing of the people taking part. In addition, the study has also been independently approved by the Oxford University Hospitals NHS Foundation Trust Research and Development Department and the Medicines and Healthcare products Regulatory Agency (MHRA).

So, in summary, what would happen if I decide to take part in the study?

- We would ring you to check that it is appropriate to include you in the research.
- You would then attend a screening visit at the CCVTM where you would have a blood test and urine test (and a pregnancy test for women). These are to assess your eligibility for the study.
- Following satisfactory screening results you would be enrolled into the study.
- You would be vaccinated with either two doses of Bexsero® or Trumenba® vaccines.
- The first vaccination would occur at your first visit post-screening and the second, six months after this.
- Your total study participation would be up to 13 months after the start of the study.

What do I do now?

Thank you for considering taking part in this study. You do not need to make a final decision straight away. If you wish to discuss any element of the study further, then please contact us by either

- telephone **01865 611400**
- website **http://trials.ovg.ox.ac.uk/trials/vambox**
- email **info@ovg.ox.ac.uk**

Yours sincerely,

Prof Andrew J Pollard
Professor of Paediatric Infection & Immunity
Honorary Consultant Paediatrician

Prof Brian Angus
Clinical Tutor in Medicine
Honorary Consultant Physician

Dr Blanché Oguti
Lead Research Fellow

Jamie Burbage
Lead Research Nurse

Investigating a new Vaccine Against Meningitis B in OXford

VAMBOX

Informed Consent Form – Serum Standard

Participant's name: _____

Participant initials: _____

Screening number: VAM – 01 |___| |___| |___||___|

*Please **initial** in each box if you agree with the statement*

I have read the 'Investigating a new vaccine against Meningitis B in Oxford (VAMBOX)' Study Information Booklet Groups 6, 7 & 8 (Version __ . __ , dated __ __ / __ __ __ / __ __ __ __). _____

I have had the opportunity to discuss the study, to ask questions about the study and I am satisfied with the answers and explanations that have been provided. _____

I have spoken with Dr/Nurse_____ _____

I understand that I am free to withdraw from the study at any time, without having to give a reason for leaving and without affecting my medical care. _____

I have received detailed information about the treatment schedule and its importance. _____

I agree to my National Insurance (if UK citizen) or Passport number being used to register me on the Trial Over-volunteering Protection Service (TOPS). I understand that it will be stored electronically for the duration of the study. _____

I understand TOPS is a Health Research Authority database that aims to prevent healthy volunteers from taking part in too many studies. I understand that only staff at OVG and other research units can use the database and OVG may call other units, or OVG may be called, to check volunteer details. _____

I agree that if a conflict is found on TOPS, OVG can share relevant information with other research groups and source relevant information from other research groups. _____

I agree to provide my bank account details including my account name, sort code and account number for reimbursement purposes. I understand that my banking details will be stored electronically for 7 years. _____

I understand that my personal information will be shared to the extent required to process or verify eligibility of payments as described in the information booklet. _____

I agree to refrain from donating blood for the duration of the study. ☐

I agree to OVG storing my personal information as described in the information booklet. ☐

I agree to OVG taking and storing my blood samples as described in the information booklet. ☐

I agree to my anonymised data and biological samples being used and stored as described in the information booklet. ☐

I understand that some of my blood will be used to investigate the genetic factors determining the response to Meningitis B infection. ☐

I consider these samples a gift to the University of Oxford and I understand I will not gain any direct personal benefit from this. ☐

I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the study team, the University of Oxford (Sponsor), regulatory authorities or the Oxford University Hospitals NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

Women only: I understand the need to ensure that I or my partner use effective contraception one month prior to vaccination and continue to do so until 2 months after. ☐
If all of the applicable sentences above are initialed, meaning "yes", then please continue:

I voluntarily agree to take part in this study. ☐

Optional: I give permission for the study team to contact me to invite me to participate in future research by the Oxford Vaccine Group. ☐

Name: ……
Signature: …… Date: |___ ___| |___ ___| 20|___ ___|
Investigator's/Nurses name: ……
Signature: …… Date: |___ ___| |___ ___| 20|___ ___|