**Study Title:** IGHID 11911 – Cross-reactive N. gonorrhoeae Immune Responses Induced by a N. meningitidis Vaccine

**NCT number** NCT04094883
**Document Date** UNC ICF Version 1.2 dated 06/24/2020

**University of North Carolina at Chapel Hill**
**Consent to Participate in a Research Study**
**Adult Participants**

**Consent Form Version Date:** Version 1.2 dated 24 June 2020

**IRB Study #** 19-1145

**Title of Study:** IGHID 11911 – Cross-reactive N. gonorrhoeae Immune Responses Induced by a N. meningitidis Vaccine

**Principal Investigator:** Joseph Alex Duncan, MD, PhD
**Principal Investigator Department:** Medicine-Infectious Diseases
**Principal Investigator Phone number:** 919-843-0715
**Principal Investigator Email Address:** joseph_duncan@med.unc.edu

**Co-Investigators:** Marcia Hobbs, PhD; Joseph Eron Jr., MD; Michelle Floris-Moore, MD, MS; Cindy Leigh Gay, MD, MPH; Christopher Hurt, MD; David A. Wohl, MD

**Funding Source and/or Sponsor:** The North Carolina Translational and Clinical Sciences (NC TraCS) Institute

**Study Contact:** Susanne Henderson, RN, (919) 843-4375– susanne_henderson@med.unc.edu

The purpose of this study is to test whether the group B meningitis vaccine (brand name Bexsero™) induces immune responses against the bacteria that causes gonorrhea.

You will receive the benefit of protection from invasive N. meningitidis infection as a result of receiving the 4CMenB vaccine over the course of the study. The information we learn by doing this study may also help us to develop a vaccine that protects individuals from becoming infected with gonorrhea.

Participants in this study will receive two doses of the FDA-approved group B meningitis vaccine (brand name Bexsero™) at study entry and week 5 that provides protection from some bacteria that cause meningitis and serious bloodstream infections. Participants will also provide blood samples as well as pharyngeal (throat) swabs and urine samples (if male) and vaginal swabs (if female) at four separate visits (study entry, week 5, week 6, and week 7). Participants will participate in this study for up to 8 weeks.

Risks of the vaccination injection are discomfort at or around the injection site; flu-like symptoms such as fever, muscle aches and pains, or tiredness; and allergic reactions such as hives, itchy rash, shortness of breath. Risks of taking the blood samples are discomfort and/or bruising; infection, excess bleeding, clotting, or fainting are also possible. Risks of collecting pharyngeal (throat) swabs and vaginal swabs are minimal pain or discomfort.

**What are some general things you should know about research studies?**
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or study staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this study?**
The purpose of this research study is to study immune responses against *Neisseria gonorrhoeae* in humans vaccinated with the US Food and Drug Administration (FDA)-approved outer membrane vesicle (OMV)-containing *Neisseria meningitidis* vaccine known as 4CMenB (trade name Bexsero™). The bacteria that cause gonorrhea (*N. gonorrhoeae*) are highly related to some bacteria that can cause an infection of the brain known as meningitis (serogroup B *N. meningitidis*). Recently two vaccines that protect individuals from this type of meningitis were approved for use in the US by the US FDA. One of those vaccines, the 4-component MenB vaccine (4CMenB, trade name Bexsero™), has a mixture of antigens from *N. meningitidis* that are very similar to antigens from *N. gonorrhoeae*, the bacteria that causes the sexually transmitted infection known as gonorrhea. Studies of early versions of the group B meningitis vaccine that were used in other countries during meningitis outbreaks demonstrated that the rates of gonorrhea in those countries declined after the vaccines were given to a large portion of the population. The 4CMenB vaccine has been found to be safe and provides immune responses that are known to protect individuals from brain infections with *N. meningitidis*. This study will test whether receiving this vaccine also leads to immune responses against *N. gonorrhoeae*. If there are immune responses to *N. gonorrhoeae*, it remains unknown whether those responses provide any protection from infection.

You are being asked to be in the study because you are a male or female who is 18-25 years old, in good health, and agree to abstain from vaccines from study entry to 30 days after you receive the second 4CMenB vaccine.

**Are there any reasons you should not be in this study?**
You should not be in this study if:

1. You have received any vaccine directed against group B meningitis.

2. You are currently pregnant or planning to become pregnant during the study period or are breastfeeding within 28 days after you receive the second 4CMenB vaccine because the safety of the vaccine in pregnant people has not been tested.
3. You have hemophilia or other bleeding disorders.
4. You have a medical condition or take medications that reduce your immune responses to vaccines such as cancer or steroid pills.
5. You are known to have active HIV, Hepatitis B, or Hepatitis C infection.
6. You have received any licensed vaccine within 30 days before you enter the study.
7. You have donated blood or blood products within 30 days before study vaccination, or plan to donate blood at any time during the study and up to 30 days after the last blood draw on the study.

**How many people will take part in this study?**

This study is only being done at UNC. There will be approximately 15 people in this research study.

**How long will your part in this study last?**

If you decide to be in this study, you will be in the study for up to 8 weeks.

**What will happen if you take part in the study?**

***Screening and/or Enrollment (Entry) Visit***

If you agree to be in the study today, we will:

- Explain the study procedures
- Ask you to sign this Informed Consent form
- Ask for your contact information
- Obtain demographic data (birthdate, race, ethnicity, gender at birth, current gender identity)
- Ask you about your medical history including medicines you are taking or have taken
- Take your vital signs [weight, heart rate, blood pressure, temperature, and respiration (breathing) rate]
- Perform a targeted physical exam
- Ask you a series of health-related questions to confirm your eligibility for the study
- If you are a female of childbearing potential, we will do a urine pregnancy test to make sure you are not pregnant before enrolling on the study.
- Provide you with study contact information
- Provide you with participant reimbursement

The screening visit will last about 1½ hours.

If you are found eligible, you may be enrolled at this same visit or come back for a separate enrollment (entry) visit, and the following procedures will be completed:

- Ask you whether you have recently been hospitalized or needed to see a doctor for a new medical problem since your last visit, are taking new medicines, or have had a recent fever or other symptoms of a new infection. This is called an Acute Illness Assessment.

- Take your vital signs [heart rate, blood pressure, temperature, and respiration (breathing) rate] and update your medical history and medications you are currently taking – only if not already done at screening on the same day,
- If you are a female of childbearing potential, we will do a urine pregnancy test to make sure you are not pregnant before enrolling on the study. This test will only be performed if your test at screening was on a different day.
- Draw blood sample (total collection volume is up to 60 mL or about 4 Tbsp)
- Collect pharyngeal (throat) swab
- Collect urine sample (if male)
- Self-collect vaginal swab (if female)
- Administer 4CMenB vaccine by an injection in the deltoid region of the upper arm or the higher front area on one side of the thigh
- Schedule Visit 2 (Week 5) of this study
- Provide you with participant reimbursement

The enrollment (entry) visit will last about one hour. If both the screening visit and the enrollment (entry) visit are done on the same day, they will last a total of about 2½ hours.

***Telephone Contact***

The study coordinator will contact you by telephone 2-3 days after your vaccine injection at the enrollment (entry visit) to determine whether any side effects have occurred. This phone contact will last about 15 minutes.

***Week 5 Visit***

The following procedures will be completed:

- Perform an Acute Illness Assessment as described above.
- Update your medical history and medications you are currently taking
- Perform a targeted physical exam
- Take your vital signs [weight, heart rate, blood pressure, temperature, and respiration (breathing) rate]
- If you are a female of childbearing potential, we will do a urine pregnancy test to make sure you are not pregnant before collecting any blood, urine, or pharyngeal (throat) samples and administering the 4CMenB vaccine.
- Draw blood sample (total collection volume is up to 60 mL or about 4 Tbsp)
- Collect pharyngeal (throat) swab
- Collect urine sample (if male)
- Self-collect vaginal swab (if female)
- Administer 4CMenB vaccine by an injection in the deltoid region of the upper arm or the higher front area on one side of the thigh
- Schedule Visits 3 and 4 (Weeks 6 and 7) of this study
- Provide you with participant reimbursement

This visit will last about one hour.

***Telephone Contact***
The study coordinator will contact you by telephone 2-3 days after your vaccine injection at the Week 5 visit to determine whether any side effects have occurred. This phone contact will last about 15 minutes.

***Week 6 and Week 7 Visits***
The following procedures will be completed:
- Update your medical history and medications you are currently taking
- Perform a targeted physical exam
- Take your vital signs [weight heart rate, blood pressure, temperature, and respiration (breathing) rate]
- Draw blood sample (total collection volume is up to 60 mL or about 4 Tbsp)
- Collect pharyngeal (throat) swab
- Collect urine sample (if male)
- Self-collect vaginal swab (if female)
- Provide you with participant reimbursement

These visits will last about 30-45 minutes.

***Specimens and specimen collection:***
- At each visit, approximately 60 ml (approximately 4 tablespoons) of blood will be drawn by a trained phlebotomist using a sterile needle inserted into a vein in your arm.
- Up to 7 separate tubes will be obtained from a single needle stick.
- The blood draw procedure will be conducted a total of four times over the entire time you participate in the study.
- At each visit, we will collect a throat swab by asking you to do the throat swab yourself or a study doctor or nurse will take a swab (like a long Q-tip or cotton bud) and wipe the inside of the back of your throat. If you are asked to collect the sample, we will provide instructions and a swab for collection.
- If you are a male, we will collect a urine sample. You will be asked to urinate in a cup that is provided for this study.
- If you are a female, we will ask you to do a vaginal swab yourself. You will be given instructions and a swab for collection.
- The blood and other samples you provide will be tested for antibodies and immune cells that recognized antigens from the bacteria *N. gonorrhoeae* and *N. meningitidis*.
- If you give permission to store your specimens by signing the separate consent form for storing biological specimens with identifying information, samples will be stored for as-yet-undesignated tests in the future which does not include genetic testing.
- The stored specimens will be used only for studies that have been approved by a human subjects protection committee, and no information will be released to other researchers that could enable them to connect your name to the specimens.
- If you do not give permission for specimen storage, your samples will be destroyed at the end of the study.

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge. You will receive the benefit

of protection from invasive N. meningitidis infection as a result of receiving the 4CMenB vaccine over the course of the study. The information we learn by doing this study may also help us to develop a vaccine that protects individuals from becoming infected with gonorrhea.

**What are the possible risks or discomforts involved from being in this study?**

The vaccination injection has the potential to cause the following side effects (the risks of these side effects are listed as percentages):

- Redness (~45%), pain (~83%) , swelling (~29%), itching, bruising, tenderness, temporary ache, or hardening or formation of a crust or scab at or around the injection site
- Flu-like symptoms such as fever (~5%), chills, muscle aches and pains (~45%), joint pain (~12%), headaches (~32%), nausea (~17%), vomiting, sweating, tiredness (~34%)
- Allergic reactions such as hives, itchy rash, shortness of breath

Side effects without an indicated frequency of occurrence, occurred with less than 2% frequency.

The risks of having blood taken include discomfort, minor swelling or bleeding, or bruising, and rarely infection, vein or blood clots where the needle enters the body. The risk of infection or blood clots after blood draw is less than 1%. Blood drawing may also infrequently cause a feeling of lightheadedness or fainting.

This study might involve minimal pain or discomfort when swabs are collected from the throat or vagina.

In addition, there may be uncommon or previously unknown risks. You should report any problems to the researchers.

Urine pregnancy tests will be done on all females who might be able to get pregnant at the screening and/or enrollment (entry) visit(s) and at the Week 5 visit. These pregnancy tests will be paid for by the study.

**If you choose not to be in the study, what other treatment options do you have?**

You do not have to be in this research study in order to receive treatment; you may obtain vaccines from your health care provider without participating in this study.

**What if we learn about new findings or information during the study?**

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

**How will information about you be protected?**

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this

research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

By signing this informed consent document, you agree that some of the information generated by participating in this study and/or a copy of the consent form may be included in your medical record and that this information may be viewed by other physicians or caregivers who provide healthcare services to you. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. Additionally, the information may be shared with your medical insurance plan if the research services provided are billed to your insurance.

**What will happen if you are injured by this research?**

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researchers will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries.

If you think you have been injured from taking part in this study, please call Dr. Alex Duncan at his pager number, 919-216-2158 – a 24 hour phone number. Since this is a pager number, you will need to enter your phone number when you call him, and he will call you back and will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

**What if you want to stop before your part in the study is complete?**

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

**Will you receive anything for being in this study?**

You will be receiving a total of up to $130.00 for taking part in this study. The reimbursement provided at each study visit is as follows: Screening Visit - $20.00; Enrollment (Entry) Visit - $20.00; Week 5 Visit - $30.00; Week 6 Visit - $30.00; Week 7 Visit - $30.00. You will also receive parking vouchers to cover your parking at each study visit.

**Will it cost you anything to be in this study?**

It will not cost you anything to be in this study.

**What if you are a UNC student?**
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

**What if you are a UNC employee?**
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

**Who is sponsoring this study?**
This research is funded by the North Carolina Translational and Clinical Sciences (NC TraCS) Institute. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on *www.clinicaltrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board (IRB) at 919-966-3113 or by email to IRB_subjects@unc.edu.

**IRB Study #** 19-1145

**Title of Study:** IGHID 11911 – Cross-reactive N. gonorrhoeae Immune Responses Induced by a N. meningitidis Vaccine

**Principal Investigator:** Joseph Alex Duncan, MD, PhD

**Participant's Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent