UAB IRB
Approved
13-Sep-2024
until
02-Jul-2025

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: A Phase II randomized, observer-blind, placebo-controlled study, to assess efficacy of meningococcal Group B vaccine rMenB+OMV NZ (Bexsero) in preventing gonococcal infection (DMID Protocol No. 19-0004)

UAB IRB Protocol #: IRB-300005422

Principal Investigator:
Jodie Dionne, MD, MPH
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Birmingham, Alabama 35294-0007
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Sponsor: National Institutes of Health (NIH), National Institutes of Allergy and Infectious Diseases (NIAID), and Division of Microbiology and Infectious Diseases (DMID). Glaxo SmithKline (GSK) is providing the study product.

Sponsor Protocol #: DMID 19-0004

Emergency Telephone Contact Information
During the business hours 8 am - 5 pm (M-F), call [redacted]
After business hours and on weekends, please page study PI Dr. Dionne by dialing the Call Center at [redacted] and asking to page number [redacted]

General Information	You are being asked to take part in a research study and your participation is completely voluntary. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to learn if a vaccine (Bexsero) that is given as two shots (injections) to prevent spinal meningitis might also work in preventing gonorrhea.
Duration & Visits	You will be in this study for 16 months. Including today's screening visit, there will be a total of eight scheduled study visits and one phone call. There may also be unscheduled visits as needed.
Overview of Procedures	This study will include injections, blood drawn from the arm, urine collection and vaginal or urethral, anal and throat swabs.
Risks	The most common risks include injection site soreness and discomfort from blood draw and swab collection.
Benefits	There may be no direct benefit to you by participating in this study.
Alternatives	If you do not want to take part in the study, you may have access to Bexsero through health care outside this study.

Purpose of the Research Study

The main purpose of this study is to learn if a vaccine that is given as two shots (injections) to prevent spinal meningitis (an infection of the lining of the brain and spinal cord caused by *Neisseria meningitidis* type B) might also work in preventing gonorrhea (caused by *Neisseria gonorrhoeae*). The vaccine we plan to use in this study is called Bexsero and has been approved by the US Food and Drug Administration (FDA) and other countries for the prevention of meningitis.

This study also has a placebo, a safe, inactive substance that looks like the study vaccine but contains no medication. You may receive the placebo instead of the active vaccine. You may enter the study if you do not care whether you receive the vaccine or the placebo. The vaccine and the placebo are both called "study product". You will not know which study product you are assigned to get. The study product is given as a shot in the muscle in your arm. You will receive two shots, given as one shot at each of two visits two months apart.

This study will enroll approximately 2650 men and women, 18-50 years old, from clinics in the United States, and international sites in Thailand and Malawi. Approximately 300 adults will be enrolled at UAB.

Study Participation & Procedures

The study doctor will discuss with you your responsibilities as a participant. If you choose to enroll in the study and sign this consent form, the following will happen:

Study Visit 0 – Screening (Today)(1.5 hours):

- We will ask you a few questions about yourself. These will include questions about your age, race, and ethnicity, medical and sexual history, medicine use, and current symptoms. Your answers will be kept confidential.
- You will be asked to provide detailed contact information (i.e. telephone number(s), email, and address). The study staff will use the contact information to follow up with you.
- Collect a urine sample to test for pregnancy, as applicable. The pregnancy test must be negative for you to be able to participate in this study. If you are breastfeeding, you cannot participate in the study.
- Study staff will perform a short physical exam.
- Study staff will collect urine or vaginal swab and one swab from each location: throat and rectum, to test for STI.
- Collect 2 teaspoons of blood from your arm for tests to check your blood, kidney, and liver function. If you have HIV, results of a recent CD4 cell count will be obtained. If recent results are not known or unavailable, then an additional 1.5 teaspoons of blood will be collected to check your CD4 cell count.
- If you test positive for gonorrhea and/or chlamydia, you will be asked to return for treatment. At the treatment visit you will be asked to continue in the study by participating in a re-screen visit no sooner than 21 days after receiving your treatment. (If you agree and have a follow-up visit within 45 days of your original screening visit, the blood already collected for baseline tests will not need to be taken again.)

Study Visit 1 – Enrollment (Day 1)(2 hours):

- We will ask you if there have been any changes in your health, and medicine use since your Screening visit. You will be asked questions about your sexual history. Your answers will be kept confidential.
- You will be asked to review and update your contact information from Screening.

- Study staff will perform a targeted physical exam, including vital signs, and look at your skin where the vaccine will be given.
- You will have a urine pregnancy test done if applicable. If you are pregnant, you will not be able to participate. If you are breastfeeding, you will not be able to participate.
- Collect approximately 3 tablespoons of blood from your arm for study tests, to understand your body's response to the shot.
- If it has been more than 14 days since your Visit 0, Screening, this visit will be completed as a screening visit. We will collect urine or vaginal swab and one swab from each location: anus and throat, to test for STI. If your test results are negative, you will be asked to return for an enrollment visit. If your test results are positive, you will be treated and after treatment you will be asked to return for another screening visit for retesting.
- You will be randomized to receive an initial shot in the arm of either Bexsero or placebo. The group that you will be in will be chosen by chance (half of the participants in the study will receive Bexsero and half of the participants in the study will receive placebo). You and the study staff will not know whether you are receiving Bexsero or placebo. Only the person who gives you the shot will know what you received.
- After receiving the shot, you will be observed in the clinic for 30 minutes prior to completing the visit to make sure you do not have any reactions.
- Study staff will review the study requirements with you and will schedule Visit 2, Phone Call, as well as Visit 3, Follow-up, Dose 2.
- If you have not been tested for 14 days or more and you test positive for gonorrhea and/or chlamydia, you will be asked to return for treatment at an unscheduled study visit. During that study visit, swabs will be collected from all infection locations or based on recent exposure or reported symptoms at either the vagina or urethra (lining of the penis), and/or rectum and/or throat to learn more about the infection.

Study Visit 2 - Phone call (Day 31)(10 minutes): We will call you 30 days after your first dose of vaccine to discuss any new medical concerns.

Study Visit 3 – Follow-up, Dose 2 (Day 61) (1 hour):

- We will ask you if there have been any changes in your health, and medicine use since your Enrollment visit. You will be asked questions about your sexual history. Your answers will be kept confidential. If you meet any of the below conditions, you cannot receive the shot today and will need to come back within the set visit timeframe for the second shot:
  - Fever ≥ 38.0°C/ 100.4°F within the past 3 days;
  - Significant illness within the past 7 days (Note: a mild upper respiratory infection or mild diarrhea are allowed);
  - Receipt of any other shot within the past 14 to 28 days (Note: allowed to receive the flu shot or an authorized or approved, inactivated COVID-19 within the past 7 days).
- You will be asked to review and update your contact information from Enrollment.
- Study staff will ask if you had any problems after receiving the first vaccine dose.
- Study staff will perform a targeted physical exam, including vital signs, and look at your skin where the vaccine will be given.
- You will have a urine pregnancy test done if applicable. If you are pregnant, you will not be able to receive the second vaccine dose.
- Collect approximately 3 tablespoons of blood from your arm for study tests.
- Collect urine or vaginal swab and one swab from each location, rectum and throat, to test for STI.
- You will receive the second dose of Bexsero or placebo in your arm, depending on what your random assignment was on the Enrollment visit.
- After receiving the shot, you will be observed in the clinic for 30 minutes prior to completing the visit to

make sure you do not have any reactions.

- Study staff will schedule Visit 4, Follow-up. If you miss this visit, you will be asked to return for another visit to receive Dose 2.
- If you test positive for gonorrhea and or chlamydia, you will be asked to return for treatment at an unscheduled study visit. During that study visit, swabs will be collected from all infection locations or based on recent exposure or reported symptoms at either the vagina or urethra (lining of the penis), and/or rectum and/or throat to learn more about the infection.

If you become pregnant at any time during the study, you must tell the study staff immediately. Study staff will contact you to ask about the outcome of your pregnancy. If applicable, study staff will collect information from you about your baby up until two months of age.

Study Visits 4 through 8 (Day 91, 181, 271, 361, and 451) (30 minutes each visit): Study visit procedures for Visit 4 through Visit 8 are identical and are listed below. At each three month follow-up visit, the following will occur:

- We will ask you if there have been any changes in your health, and medicine use since your last visit. You will be asked questions about your sexual history. Your answers will be kept confidential.
- You will be asked to review and update your contact information.
- Study staff will ask if you had any problems since your last visit.
- You will have a physical exam.
- Collect approximately 3 tablespoons of blood from your arm for study tests.
- Collect urine or vaginal swab and one swab from each location, rectum and throat, to test for STI.
- Study staff will schedule your next Follow-up Visit.
- If you test positive for gonorrhea and or chlamydia, you will be asked to return for treatment at an unscheduled study visit. During that study visit, swabs will be collected from all infection locations or based on recent exposure or reported symptoms at either the vagina or urethra (lining of the penis), and/or rectum and/or throat to learn more about the infection.

Unscheduled Visit (30 minutes each visit):

You may be asked to return to the clinic between scheduled visits if you have continuing or new symptoms (especially those that might suggest you have an STI, including new discharge from or discomfort at the vagina, rectum or penis), tested positive for gonorrhea and/or chlamydia, if any symptoms get worse, or if the study staff feel you should be seen for any reason. At the visit, the following study procedures may be repeated:

- We will ask you if there have been any changes in your health, and medicine use since your last visit. You will be asked questions about your sexual history. Your answers will be kept confidential.
- You will be asked to review and update your contact information.
- Study staff will ask if you had any problems since your last visit.
- You will have a physical exam including vital signs if needed based on any problems you report.
- Collect approximately 3 tablespoons of blood from your arm for study tests.
- Collect urine or vaginal swab and one swab from each location: rectum and throat, to test for STI.
- If you test positive for gonorrhea or chlamydia, you will be asked to return for treatment at an unscheduled study visit. During that study visit, swabs will be collected from all infection locations or based on recent exposure or reported symptoms at either the vagina or urethra (lining of the penis), and/or rectum and/or throat to learn more about the infection.

Additional Information:

The private information or biospecimens collected as part of the research will not be used or distributed for future research studies even if identifiers are removed. However, you will have the option to allow use of your information and biopsecimens for future research.

The biospecimens obtained from you for this research, which may or may not include your identifiable private information, may be used for commercial profit. There are no plans to provide financial compensation to you should this occur.

The clinical results (including individual research results) will be shared with you by phone or at a study visit.

Risks and Discomforts

There are risks associated with participation in any research study. The vaccine that we are studying, Bexsero, is FDA approved in the US for use in people 10 through 25 years of age to prevent one type of spinal meningitis. The table below outlines the most common and/or significant risks of this study. In addition, you may become embarrassed, worried, or nervous when answering questions about your sexual activity. You may feel worried or anxious while waiting for your test results. Trained study staff are available to help you deal with any feelings or questions you have. There may also be risks that are unknown at this time. You will be given more information if other risks are found.

Study procedure	Risk
Participation in Research	Inconvenience, extra time, confidential information provided could be accidentally shared with others
Study questionnaires	Uneasiness, embarrassment
Use of study product	Injection site reactions like soreness, redness, or swelling where the shot is given, tiredness, fatigue, headache, muscle or joint pain, fever, chills, nausea, or diarrhea can happen. Some of these reactions occur in more than half of the people who receive the shot. People sometimes faint after a shot. As with any medicine, there is a very remote chance of a severe allergic reaction. Enlarged lymph nodes have been reported but because this possible side effect was voluntarily reported after the vaccine became available to the general public, we can't tell how often it occurs or if it is related to the vaccine.
Blood drawing	Drawing blood may cause temporary discomfort from the needle stick, feeling light headed or faint, bruising, and rarely, infection.
Swab collection	Collection of vaginal or urethral, anal and throat swabs may be uncomfortable.

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

The main results from this study will be shared with participants when the study ends, and participants will learn if they received the vaccine or placebo.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child

We do not know if the study drug will affect mother's milk or an unborn fetus. Therefore, breastfeeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, there may be risks to the embryo or fetus that are unknown at this time. Women who can become pregnant must take a pregnancy test before the start of the study.

Benefits

There may be no direct benefit to you by participating in this study. You may benefit by finding out more about the cause of any genital symptoms you are experiencing and finding out if you have a sexually transmitted infection (STI), gonorrhea and chlamydia. If you receive the active study product (Bexsero vaccine) but not placebo, you may receive protection against the form of spinal meningitis caused by *Neisseria meningitidis* type B.

You will be assigned to a group by chance, which may prove to have more or less benefits than the other study group.

Alternatives

You do not have to participate in this study. There is currently no vaccine available for preventing gonorrhea. You may have access to Bexsero through health care outside this study; however, you should not enter this study if you want or need to receive Bexsero or another vaccine for *Neisseria meningitidis* type B meningitis during your participation in the study.

The study doctor will discuss with you the alternatives to participation and their risks and benefits.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Because it is very important that we can contact you during the study, you will be asked to provide contact information like your address, phone numbers, and email address. We ask for at least two additional contacts (e.g., family member or friend) who know how to reach you or would have new contact information for you. The study staff may call your contact(s) if your numbers are changed or disconnected. We will not give out private information if we need to get in touch with your contacts.

Participation in research may involve a loss of privacy. We will do our best to make sure that your personal information is kept private. Your records will be kept as confidential as is possible under the law. The research records will identify you by a unique subject number, not your name. Your individual identity will not be used in any reports or publications resulting from this study.

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but

not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this clinical trial will be available on http://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. The ClinicalTrials.gov identifier is NCT04350138.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. The investigators may use or disclose, for purposes of this study, identifiable information (which may include identifiable medical information) related to your being in this study for a minimum of 2 years after the study is completed.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., study monitors, auditors and GSK and their designees).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the US Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries (e.g. Thailand and Malawi regulatory authority)
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research *is* covered by a Certificate of Confidentiality from the NIH. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other

proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH, NIAID, and DMID which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

As part of this study, you will be tested for gonorrhea and chlamydia. If the results show that you are positive for gonorrhea or chlamydia, the study staff will tell you the results. The study staff will be required to give your name to the Alabama Department of Public Health if you test positive because this is the law.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study staff. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others if necessary in order for the research study data to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

You do not have to be a part of this study. Your participation in this study is completely your choice. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you can discontinue participation at any time without penalty or loss of benefits to which you would otherwise be entitled. If you no longer want to be in this study and end your participation, just tell the study staff. Your decision will not affect your relationship or the care you are entitled to receive at the Sexual Health Research Clinic (SHRC) or 1917 Clinic. However, you should return to see the study doctor for referral and follow-up care.

If you decide not to allow the use of your private information, you will be removed from further participation in this study. Any information obtained during your taking part in this study may continue to be used.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Being withdrawn early
The study doctor has the right to take you out of the study if:

- the study (in the opinion of the doctor) would pose a health risk to you
- you do not follow the study requirements
- the study is stopped
- you are no longer eligible for the study

Early Termination Visit
If you decide to stop being part of the study before the final study visit, Visit 8, with your permission you will be asked to return to the clinic for a visit. At that visit, the items listed above for Visit 8 will occur.

Cost of Participation

There will be no cost to you to take part in this study. Your insurance will not be billed for any of the research procedures however, treatment or procedures done according to usual care may be charged to your insurance.

The study product (Bexsero or placebo) will be provided to you free of charge.

Payment for Participation

If you complete the required study procedures, you will get the following amounts at the end of each visit for your time, transportation, and other expenses:

V0, Screening (today): [redacted]
V1, Enrollment, Dose 1 (Day 1): [redacted]
V2, Phone Call (Day 31): [redacted]
V3, Follow-up, Dose 2 (Day 61): [redacted]

V4, Follow-up (Day 91): [redacted]
V5, Follow-up (Day 181): [redacted]
V6, Follow-up (Day 271): [redacted]
V7, Follow-up (Day 361): [redacted]
V8, Follow-up/Final Study Visit (Day 451): [redacted]

Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

If you complete all screening, enrollment, and follow-up visits you will receive a total of [redacted]. You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Payment for Research-Related Injuries

The staff at the SHRC and 1917 Clinic make efforts to prevent and treat any injuries that might happen. If you think you are hurt because of the study, contact the study staff right away.

Emergency care for injuries related to this study will be done by the staff of SHRC or 1917 Clinic. It is possible that 1917 Clinic may bill your insurance for the cost. If your injury needs more medical care, you may be responsible for the costs.

UAB and the NIH will not pay for treatment or provide any compensation in the case of injury. No long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the US Federal Government.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional

Secondary Research Use of Identifiable Private Information and/or Identifiable Biospecimens

With your approval, the blood samples and data collected during the study visits will be kept by DMID after the end of the study and may be used for secondary (future) research use for development of other drug or diagnostic products against gonorrhea. Any such future research will be performed by or in collaboration with the study investigators, DMID, and would be done in the investigators' institutions or in the institutions of their collaborators. You will not be contacted in the future when the samples are used. No genetic testing or whole genetic sequencing will be performed on these samples.

The blood samples we save for future use and the data we collect about you will be labeled with a unique subject ID, not your name address, or other information that could be used to easily identify you. . We may remove the subject ID (so that we cannot identify you) from your information or samples and use these in future research. These may be shared with other researchers or third parties without your additional consent. You will not be contacted with the results from any future testing. Results of any future research will not be given to your doctor.

Allowing us to do future research on your samples will not benefit you directly. Your samples will be kept until used up or for up to 20 years and then destroyed.

Controlled-Access Databases: Your information may be put in controlled-access databases. This means only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your information stored in these databases will not include any identifying information. We will replace identifying information with a code number. We will keep a master list that links your code number to your identifying information here at the UAB. Only certain study personnel for this study at UAB will have access to this master list. Researchers approved to access information in the controlled-access database will agree not to attempt to identify you.

Future research use of your samples and data will be conducted in compliance with applicable regulatory requirements.

Your samples used for future research may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators, the University of Alabama at Birmingham, and third parties, which may also include pharmaceutical companies for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Alabama at Birmingham, and third parties which may also include pharmaceutical companies or their agents, may realize.

You do not have to agree to allow us to collect and store your samples for future research to participate in this study.

If you decide to allow collection and storage of future use samples but then later decide that you do not want your samples stored for future use, you should contact the site Principal Investigator, Dr. Jodie Dionne at [redacted]. Your samples will be destroyed at the end of the study or removed from storage and destroyed. Only stored samples with a unique subject ID that are not used in this research can be removed or destroyed. Research that has already begun to use your samples cannot be withdrawn. For example, if some research with your samples and data has already been completed, the information from that research may still be used. If samples and data have already been shared with other study investigators, it might not be possible to withdraw your samples and data.

Permission for collecting and storing samples for secondary use (if you disagree this will not influence your chance to participate in the study):

_____ Participant Initials	I agree to allow my coded samples and study data to be used for future use for development of other drug or diagnostic products against gonorrhea.
_____ Participant Initials	I do not agree to allow my coded samples and study data to be used for future research.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor, Jodie Dionne, by dialing [redacted] during the business hours 8 am - 5 pm (M-F). After business hours and on weekends, please page Dr. Dionne by dialing the Call Center at [redacted] and asking to page number [redacted].

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at [redacted] or toll free at [redacted] Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. I understand that the UAB OIRB cannot provide information regarding the study vaccine in this study.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

The above information has been explained to me. I understand that I am encouraged to ask questions and talk about concerns or complaints about this research study. Questions, concerns, or complaints I have in the future will be answered by study staff. I understand that I may always ask questions. By signing this form, I agree to participate in this research study as described above. A copy of this consent form will be offered to me.

_____
Printed Name of Participant

_____	_____	_____AM/PM
Participant's Signature	Date	Time

Certification of Informed Consent:
I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date