

# **Informed Consent Form**

Effectiveness of Azithromycin in Eradicating Nasopharyngeal Carriage of  
N. meningitidis

IRB Approval Date: October 2, 2025

NCT06618534

## **You Are Being Asked to Be in a Research Study**

### **Concise presentation of key concepts**

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 1,120 people who are being studied at Emory.

### **Why is this study being done?**

This study is being done to answer the question: Is the antibiotic Azithromycin effective in clearing carriage of the *Neisseria meningitidis* bacterium (the bacteria that can cause meningitis)? You are being asked to be in this research study because you live with other Emory students.

### **Do you have to be in the study?**

It is your choice to join this research study. You do not have to be in it. Before you choose, take time to learn about the study.

### **What do you have to do if you choose to join this study?**

If you qualify and choose to join the study, you will participate for 30 days (1-3 study visits and 1 or 2 phone calls depending on your responses to questionnaires and results of samples we collect during this study). The researchers will ask you to do the following: answer questionnaires, collect throat swab for testing, and take a one-time dose of an FDA-approved antibiotic called Azithromycin if results of your throat swab are positive for *Neisseria meningitidis*. All these procedures will be paid for by the study.

### **How is this study going to help you?**

This study is not intended to benefit you directly. You may benefit from participating in the study by finding out if you test positive for *N. gonorrhea*, a bacterium that is similar to *N. meningitidis* that can also be found in the throat, in which case the study team will notify you and provide information on where you can get treated.

### **What are the risks or discomforts you should know about before deciding?**

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Side effects of the medication azithromycin which may include: nausea, vomiting, diarrhea

- Slight temporary physical discomfort when throat swab is collected
- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled “What are the possible risks and discomforts?”

### **Alternatives to Joining This Study**

The alternative to joining this study is not to participate in this study.

### **Costs**

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

There is more information in the “Costs” section further below.

### **What Should You Do Next?**

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Take time to think about this and talk about it with your family and friends.

**Emory University**  
**Consent to be a Research Subject / HIPAA Authorization**

**Title:** Effectiveness of Azithromycin in Eradicating Nasopharyngeal Carriage of *N. meningitidis*

**IRB #:** STUDY00008433

**Principal Investigator:** Paulina A. Rebolledo, MD, MSc  
Department of Medicine, Division of Infectious Diseases

Telephone: [REDACTED]  
E-mail address: [REDACTED]

Address: [REDACTED]  
[REDACTED]

**Sponsor:** Center for Disease Control and Prevention (CDC)

**Introduction**

You are being invited to be part of a research study, please read this form carefully. This form gives you information to help you decide whether to be in the study. Being in the study is voluntary. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

**What is the purpose of this study?**

Meningococcal disease, caused by the bacterium *Neisseria meningitidis*, is a serious illness. It is a leading cause of bacterial meningitis in children and adolescents in the United States. Meningitis is an infection of the fluid surrounding the brain and spinal cord. Meningococcal bacteria can also cause infections in the bloodstream. Meningococcal

infections can affect individuals aged 18-25 who live in close quarters such as university dormitories or other forms of student housing, and prompt treatment with antibiotics is necessary. Individuals who have come into close contact with sick individuals are also treated with antibiotics to minimize the risk of getting sick. Meningococcal vaccines are recommended in the United States, but because the duration of protection is limited, they cannot prevent all cases of the disease.

While meningococcal bacteria can make people sick, they can also live in some people's throats without making them sick. People usually do not know they are even there. This is known as "carriage" or "carrying the bacteria." At any given time, 5% to 10% of people may carry meningococcal bacteria in their nose and throat. This number may be higher during the winter and in crowded settings where germs are likely to spread. Meningococcal bacteria are spread through saliva, coughing or sneezing. When people who have the bacteria come in close contact those who have not been exposed to it, they can spread the bacteria.

Since 2020, the number of patients with meningococcal disease who did not respond to the standard antibiotic, ciprofloxacin, has increased. We do not know how well other antibiotics such as rifampin, ceftriaxone, or azithromycin will work. Because azithromycin is often used to treat common infections, we want to know if it will work to get rid of meningococcal bacteria.

The purpose of this study is to see if azithromycin will get rid of meningococcal bacteria in those who are carrying it. We plan to enroll 1,120 people in this study.

### **How do I qualify for the study?**

To join this study, you must:

- be between the ages of 18 and 25
- provide written informed consent
- agree to join the study and attend the study visits
- be an Emory University graduate student living in Emory University affiliated housing

OR

- be an undergraduate student attending Emory University
- live in housing with other Emory students

you must not:

- be a University teacher or staff
- be pregnant or breastfeeding
- have a history of allergic reactions to azithromycin
- have taken antibiotics in the last 30 days
- have any symptoms of being sick right now

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

You will be in the study for about 30 days. You will have 1 to 3 study visits, and 1 or 2 phone calls depending on your responses to questionnaires and results of samples we collect during this study. If necessary, there may be an unscheduled phone call or visit to check on you. You will complete questionnaires and we will swab your throat. A throat swab is similar to a "Q-tip" touching the back of your throat (like the test for strep throat that you may have gotten before). Using the cotton swab, we will rub the tonsil area and back of throat for a

few seconds. If we find that you have the bacteria in your throat, we will ask you to come back for another throat swab and to give you a single dose of the antibiotic azithromycin. After you take the antibiotic, we will schedule you for another in-person visit to collect a third and final throat swab.

There is a very low chance of getting sick from carrying the meningococcal bacteria, so even if it is found in your throat at the last visit you will not need extra antibiotics. In standard medical care, doctors do not give antibiotics to carriers unless it is for a research study, an outbreak, or if you've been in close contact with someone who has the disease. You will not need to seek additional medical care for carriage at the end of your participation in the study. As stated above, we will look for meningococcal bacteria when testing your throat swab. However, a related bacterium called *Neisseria gonorrhoeae* (which causes gonorrhea) may also be found during this testing because these bacteria are closely related to the ones that cause meningitis. If *Neisseria gonorrhoeae* is found in your throat swab, treatment is very important. You will be contacted privately by our study team to provide guidance and resources where you can receive treatment. Any positive *Neisseria gonorrhoeae* test results will be reported in a confidential manner to the Georgia Department of Public Health as per standard reporting guidelines for *Neisseria gonorrhoeae*. Positive results for *Neisseria gonorrhoeae* will not be shared with your parents, other people at Emory University, or any other group without your permission. If you have any questions, you can reach us using the contact information at the bottom of the form.

#### **Visit 1, Day 1 [≈ 60 min]**

- You will sign the consent form
- We will collect contact information for follow-up and study visit reminders.
- You will complete an online questionnaire
- We will swab your throat.
- We will review your vaccination records in the Emory University Health Center records and the State Immunization Registry.

We will test the throat swab to see if you have meningococcal bacteria. If you do not, the study will end. If you do have the bacteria, you will be called within 3 to 6 days to schedule Visit 2.

#### **Visit 2 (Between Day 4 and Day 10) [≈ 60 min]**

- You will complete an online questionnaire.
- We will swab your throat.
- We will give you a dose of azithromycin.
- We will schedule your final study visit.

#### **Visit 3 (Between Day 14 and Day 28) [≈ 30 min]**

- You will complete an online questionnaire.
- We will swab your throat.
- We will ask if you have had any side effects from the azithromycin antibiotic.

## Unscheduled phone call (Between Day 7 and Day 30) [≈ 15-30 min]

If at any point in the study one of your throat swab results is positive for *Neisseria gonorrhoeae*, a bacterium similar to *Neisseria meningitidis* that causes gonorrhea, a study staff member will contact you to notify you of your result, counsel you, and assist in referring you to a provider for treatment.

## Unscheduled Visits

You may be asked to come back to the study site at other times if needed, for example, if you have symptoms or illness that should be evaluated before the next scheduled visit. The study doctor will decide what additional steps will be needed after reviewing any symptoms.

## What are the possible risks?

### Study Drug:

Azithromycin is a commonly used antibiotic that is FDA approved for mild to moderate infections such as bacterial sinusitis, urethritis, pharyngitis, and others. Because Azithromycin has been extensively studied and has been FDA approved in the US since 1991, it is unlikely but still possible that there may be side effects from the study drug or procedures that are not known at this time.

Potential common side effects (occurring in more than 1 in 100 people and typically seen with longer and higher doses of azithromycin) could include:

- Nausea, loss of appetite, and/or vomiting  
Note: If vomiting occurs less than one hour after taking this medication, you may need to be re-treated
- Abdominal pain
- Diarrhea/loose stools
- Headache
- Feeling dizzy or tired
- Changes to sense of taste

Serious side effects are rare and happen in less than 1 in 1,000 people and generally involve longer courses of azithromycin. Serious side effects may include:

- Faster or irregular heartbeat
- Yellowing of the skin or the whites of your eyes as signs of liver or gallbladder problems
- Ringing in the ears, temporary hearing loss, or feeling unsteady on your feet
- Severe stomach or back pain as a sign of inflammation of the pancreas
- Severe diarrhea accompanied with blood or mucus with/without muscle cramps
- Vaginal infection or irritation

A rare skin reaction that can happen as a response to medications that causes red spots or bumps Allergic reactions to azithromycin are rare, but these reactions can be very serious. Individuals who are allergic to Azithromycin may experience:

- Trouble breathing
- Swelling in the face, mouth, and neck
- Severe skin rash, hives, or blisters

Some medications, specifically antacids (e.g., Tums, Rolaids, Gaviscon, Maalox, etc.) may affect the absorption of azithromycin. It is recommended to wait at least 2 hours after taking this medication before taking any antacids.

Other medications that could interfere with Azithromycin include:

- Blood thinners
- Cyclosporin (used to suppress immune system)
- Digoxin (used for treatment of heart problems)
- Ergotamine or ergot derivatives (used for migraine treatment)

#### Throat Swab:

You may have temporary physical discomfort during the swab.

#### Questionnaires:

The questionnaires used in this study will ask questions about your medical history and your social history like smoking status and habits. If answering these questions makes you uncomfortable, you do not need to answer any questions that you are not comfortable with.

#### Privacy and Confidentiality:

Participation in research may involve a loss of privacy. Your records will be kept as confidential as possible under the law. Individual identity will not be used in any reports or publications resulting from this trial. There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this consent form. Please ask us if you would like to know more about how your information will be protected while you are in this study.

#### Unforeseen Risks

There may be risks and discomforts we do not know about right now. It is possible that we will learn new information on the risks and discomforts of being in this study. If this happens, the study clinician will tell you about them. Then you can decide if you want to continue to be in this study or not.

**How will your study drug be provided?**

The study drug that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the study drug to you. If you have questions about the study drug, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the study drug. The number for the pharmacy is included on your study drug package, if given one.

Note: The research team for this study includes non-licensed team members who may obtain your consent, or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

**Who owns your study data and samples?**

If you join this study, you will be donating your samples and data. If you leave the study, the data and samples that were already collected will still be used for this study. Any data already collected or products that already exist at the time that you decide to leave the study will remain the property of the study investigator

**Will you benefit from the study?**

If you are in the study and test positive for *N. gonorrhea* from your throat swab, you will be counselled by the study team and referred for treatment. You will also be helping the researchers answer the study question.

**Will you be paid for your time and effort?**

You will be compensated for being in this study. You will be paid \$20 per visit for a total of \$60 if you complete all study visits. You will be paid only for the visits you complete according to the following schedule:

- \$20 for the screening and enrollment visit
- \$20 for initiation of Azithromycin treatment visit
- \$20 for follow-up visit after Azithromycin treatment

You will be paid by gift card as the preferred method of compensation and will be provided following each completed visit. We may also compensate you in the form of ClinCard if gift cards are not available. If ClinCards are utilized, you will be issued a ClinCard at the initial visit and we will ask you to keep this card so subsequent compensation amounts can be added after each additional completed visit.

A company called Greephire is working on behalf of the study to reimburse participants. Greenphire will need to collect certain personal information about you to set up your reimbursement account. The company will know you are in this study.

If you have any questions about your compensation for participation, please contact the study staff.

### **What are your other options?**

You do not have to be in this study. Please talk to the study clinician or staff member about your options before you decide whether or not you will take part in this study.

### **How will your private information be protected?**

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

### **Certificate of Confidentiality**

This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. 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 CDC 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 for

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document including research data in the medical record.

### **Storing and Sharing your Information**

We will store all the data and specimens that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data and specimens may be useful for other research being done by investigators at Emory University and/or CDC or elsewhere. We may share the data or specimens, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

### **Medical Record**

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

Emory may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will not be placed in your medical record. For this study, those items include: positive test results from your throat swab for *N. meningitidis* and subsequent analysis to better characterize this bacterium.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

### **In Case of Injury**

If you get ill or injured from this research, contact the person listed in the contact section of this form. Emory will help you get immediate medical care. However, Emory and the Federal Government (including, but not limited to, the National Institutes of Health as applicable) do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study- related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

### **Costs**

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as described in this form, the cost of treatment for those complications may be charged to you or your insurance.

### **Withdrawal from the Study**

Your decision to take part in this study is voluntary. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. Whether or not you choose to take part in this study has no impact on the care you receive today or in the future. You can decide to stop your study participation at any point. That said, we will continue to use any information from your participation in this study up to the point you withdraw from the study. If you do decide to stop your study participation, we will ask you to please notify the study staff about this.

The Investigator or the sponsor can stop your participation at any time without your consent for any of the following reasons:

- If it appears to be medically harmful to you
- If you fail to follow directions for participating in the study
- If it is discovered that you do not meet the study requirements
- If the study is canceled
- For administrative reasons

### **Student Health Records**

We are asking for your permission to look at your vaccination records. We are doing this to see if having received the meningococcal vaccine in the past is related to being a carrier of the *N. meningitidis* bacteria.

Your vaccination records are part of your Student Health Records, and they are protected under a law called FERPA (Family Educational Rights and Privacy Act). This law keeps your health and education information private.

By signing this form, you are giving us permission to access only your vaccination records for the meningococcal vaccine. We will use this information only for the purposes of this study. We will not share your vaccination records with anyone outside the study, and we will keep your information confidential.

You do not have to give us permission, and it will not affect your grades, health care, or participation in other activities at school.

If you agree to let us see your vaccination records, please sign below.

\_\_\_\_\_  
**Name of Subject**

\_\_\_\_\_  
**Signature of Subject (18 or older and able to consent)Date**

## Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

### Research-Related Treatment

This study involves research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

### IIHI that Will be Used/Disclosed:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.
- Georgia Registry of Immunization Transactions and Services (GRITS)

### Purposes for Which Your IIHI Will be Used/Disclosed:

- To conduct this research study
- To evaluate the safety and effectiveness of the drug, device and/or other intervention being studied and ensure integrity of the data
- To provide study-related treatment and facilitate payment for such treatment
- To conduct healthcare operations
- To ensure compliance with state and federal regulations and provide oversight of the study
- To determine your health, vital status or contact information should you be unreachable during the study
- For the administration and payment of any costs relating to subject injury from the study including reporting payment information to Medicare/Medicaid where applicable

### Use and Disclosure of Your IIHI That is Required by Law:

We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

### Authorization to Use IIHI is Required to Participate:

By signing this form, you give us permission to use and disclose your IIHI for this research study.

### People Who will Use/Disclose Your IIHI:

- The Principal Investigator and the research staff
- The sponsor of the research, its agents, study monitors and contractors including laboratories if applicable
- Institutional Review Boards (people who provide ethical review of research)
- Other Emory offices and persons who watch over the safety, effectiveness and conduct of the research
- Government agencies that regulate the research as applicable to this study (e.g. regulatory agencies within and outside the United States such as the Office for Human Research Protections, Food and Drug Administration and Veterans Administration)

In certain cases where a researcher moves to a different institution, your IIHI may be disclosed to that new institution and their oversight offices. The IIHI will be disclosed in a secure manner and under a legal agreement signed by both institutions to ensure it continues to be used under the terms of this consent and authorization.

### **Expiration of Your Authorization**

Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

### **Revoking Your Authorization**

If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: Dr. Paulina Rebolledo via email at [REDACTED] or office phone at [REDACTED].

At that point, we will stop collecting your IIHI. We may use or disclose the IIHI already collected so we can follow the law, protect your safety, make sure that the study was done properly and the data is correct. If you revoke your authorization, you will not be able to stay in the study.

### **Other Items You Should Know about Your Privacy**

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers, Sponsor, and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

### **Contact Information**

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Paulina Rebolledo via email at [REDACTED] or office phone at [REDACTED].

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or [irb@emory.edu](mailto:irb@emory.edu).

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at



<https://tinyurl.com/ycewgkke>

**Contact for Future Studies:**

We may want to contact you in the future to see if you are interested in participating in other studies. If, and when, you are contacted, you can decide then if you want to participate or not in new studies. To be able to contact you in the future, we will need to store your information in a secure password protected database at the Hope Clinic.

We may contact you about future studies by telephone, e-mail, text or mail. Please note that these methods of communication may not be secure. The risk to you is a potential loss of privacy; however, your privacy is very important to us, and we have safeguards in place to protect your information.

In the database, we plan to store selected information including but not limited to the following: your name, sex, date of birth, address, telephone number, e-mail, studies that you either screened for or enrolled in, health information so that we can match you with a study that best fits you and contact you in the future. Your decision regarding future contact will not affect your participation in this study.

Please place your initials below (select only ONE option):

\_\_\_\_\_ YES, you may contact me about future studies  
Initials

\_\_\_\_\_ NO, please do not contact me about future studies  
Initials

Consent

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***TO BE FILLED OUT BY SUBJECT ONLY***

**Print** your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

\_\_\_\_\_  
**Name of Subject**

\_\_\_\_\_  
**Signature of Subject (18 or older and able to consent)**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**

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***TO BE FILLED OUT BY STUDY TEAM ONLY***

\_\_\_\_\_  
**Name of Person Conducting Informed Consent Discussion**

\_\_\_\_\_  
**Signature of Person Conducting Informed Consent Discussion**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**