Doxy-PEP: Dose-Ranging Study of Persons Receiving Doxycycline

NCT05853120

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STUDY00005552

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 40 people who are taking part at Emory.

Why is this study being done?
This study is being done to answer the question: How well does doxycycline taken by mouth absorb into the tissues of the rectum and vagina. You are being asked to be in this research study because you are between the ages of 18-59 and are generally healthy.

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 about 3 weeks (13 study visits). The researchers will ask you to do the following: take the study drug, doxycycline, undergo blood draws, swabs and biopsy procedures. All of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. This study is not intended to benefit you directly.

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:

- risks of doxycycline, some of which include diarrhea, vomiting and allergic reaction
- minor pain or bruising at the blood draw site
- some rectal bleeding
- discomfort from the rectal sampling procedure
- discomfort from the vaginal sampling procedure
- vaginal bleeding and/or discharge
- infection
- loss of privacy or 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
Since this is not a treatment study, the alternative is not to participate.

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.

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 and Grady Health System
Consent to be a Research Subject

Title: Doxy-PEP: Dose-Ranging Study of Persons Receiving Doxycycline

IRB #: 5552

Principal Investigator: [redacted]

Study-Supporter: Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention

Introduction

You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **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?

The purpose of this study is to understand how well doxycycline taken by mouth gets to the tissues of the rectum and vagina. Researchers think doxycycline could be used to treat sexually transmitted infections (STIs) caused by bacteria. To understand better, they want to see how well doxycycline reaches the tissues affected by STIs. This study is designed to test the levels of doxycycline in rectal and vaginal tissues. We will enroll 40 participants in this study: 20 people assigned male at birth (AMAB) and 20 people assigned female at birth (AFAB). One group of participants will receive 100mg doses of doxycycline while another group will receive 200mg doses.

What will you be asked to do?

Participants in this study will complete 13 study visits over the next 3 weeks. The study visits are detailed below.

Screening

If you agree to take part in this study, this visit will occur on the same day you sign this form. At this visit you may complete the following activities:

- Answer questions about your medical history and medications
- Complete a brief questionnaire about your sexual behavior history
- Have a physical exam done
- Pregnancy test (if you are of childbearing ability)
- HIV testing

- Blood draw for other lab tests – 17 mL (about 4 teaspoons)
- Self-collected vaginal and/or rectal swab and urine sample for gonorrhea and chlamydia testing

Based on the results of the Screening Visit activities, the study staff will determine if you are a good fit for the study or not. If you are, you will be asked to come back for Visit 1a.

Visit 1a (Day 0) – Enrollment
This visit will take place within 42 days (6 weeks) after the Screening Visit. During this visit, the following activities will be completed:

- Blood draw **–** up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by participant – rectal, vaginal (if applicable) and throat
- First dose of doxycycline

Visit 1b (Hour 2-4/Day 0)
This visit will take place 2-4 hours after the first dose. During this visit, the following activities will be completed:

- Blood draw **–** up to 10 mL (about 2 teaspoons)
- Swab collection done by participant – rectal, vaginal (if applicable) and throat

Visit 2 (Hour 24/Day 1) – Biopsy Visit
This visit will take place 24 hours (1 day) after the first dose. During this visit, the following activities will be completed:

- Have a brief physical exam
- Rapid HIV test (if needed, per study staff)
- Blood draw – up to 10 mL (about 2 teaspoons)
- Pregnancy test (if of childbearing ability)
- Collection of urine sample
- Swab collection done by staff – urethral and glans
- Swab collection done by participant – rectal, vaginal (if applicable) and throat
- Collection of biopsy samples
    - Rectal – *only for participants without a vagina*
    - Vaginal/Cervical - *only for participants with a vagina*

Rectal Biopsy Samples: A study clinician will insert a plastic tube called a “rigid sigmoidoscope” into your rectum. Once the scope is inserted, up to 12 biopsies will be collected in which small pieces of your bowel tissue (less than ¼ inches) will be removed. It is important that you do not put anything in your rectum or bottom for 3 days before and 7 days after the procedure because you may be at a higher risk for infection while the rectum is healing.

Vaginal/Cervical Biopsy Samples: A study clinician will insert a speculum into your vagina. Once the speculum is inserted, up to 2 vaginal and 2 cervical biopsies will be collected in which small pieces of your vaginal or cervical tissue (less than ¼ inches) will be removed. It is important that you do not put anything in your vagina for 3 days before and 7 days after the procedure because you may be at a higher risk for infection while the vagina and cervix is healing.

A day or two after your biopsy procedure, one of the study staff will call you to see how you are doing, ask if you have any symptoms.

Visit 3 (Hour 48/Day 2)
This visit will take place 48 hours (2 days) after the first dose. During this visit, the following activities will be completed:

- Blood draw **–** up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by participant – rectal, vaginal (if applicable) and throat

Visit 4 (Hour 72/Day 3)
This visit will take place 72 hours (3 days) after the first dose. During this visit, the following activities will be completed:

- Blood draw – up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by staff – urethral and glans
- Swab collection done by participant – rectal, vaginal (if applicable) and throat
- Second dose of doxycycline

Visit 5 (Hour 168/Day 7) – at home dose
You will be asked to take this dose of doxycycline at home 168 hours (7 days) after your first dose. You will be asked to provide proof that you took the dose. Study staff can discuss options for how provide proof.

Visit 6 (Hour 240/Day 10) – at home dose
You will be asked to take this dose of doxycycline at home 240 hours (10 days) after your first dose. You will be asked to provide proof that you took the dose. Study staff can discuss options for how provide proof.

Visit 7a (Hour 336/Day 14)
This visit will take place 336 hours (14 days) after the first dose. During this visit, the following activities will be completed:

- Blood draw **–** up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by participant – rectal, vaginal (if applicable) and throat
- Fifth dose of doxycycline

Visit 7b (Hour 338-340/Day 14)
This visit will take place 2-4 hours after the fifth dose and 338-340 hours (14 days) after the first dose. During this visit, the following activities will be completed:

- Blood draw **–** up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by participant – rectal, vaginal (if applicable) and throat

Visit 8 (Hour 360/Day 15) – Biopsy Visit
This visit will take place 360 hours (15 days) after the first dose (T^1 = 0 hr) and 24 hours after the fifth dose. During this visit, the following activities will be completed:

- Have a brief physical exam
- Rapid HIV test (if needed, per study staff)
- Blood draw – up to 10 mL (about 2 teaspoons)

- Pregnancy test (if of childbearing ability)
- Collection of urine sample
- Swab collection done by staff – urethral and glans
- Swab collection done by participant – rectal, vaginal (if applicable) and throat
- Collection of biopsy samples
    - Rectal – *only for participants without a vagina*
    - Vaginal/Cervical - *only for participants with a vagina*

Visit 9 (Hour 384/Day 16)
This visit will take place 384 hours (16 days) after the first dose. During this visit, the following activities will be completed:

- Blood draw **–** up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by participant – rectal, vaginal (if applicable) and throat

Visit 10 (Hour 408/Day 17)
This visit will take place 408 hours (17 days) after the first dose. During this visit, the following activities will be completed:

- Blood draw – up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by staff – urethral and glans
- Swab collection done by participant – rectal, vaginal (if applicable) and throat

Visit 11 (Hour 432hr/Day 18)
This visit will take place 432 hours (18 days) after the first dose. During this visit, the following activities will be completed:

- Blood draw **–** up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by participant – rectal, vaginal (if applicable) and throat

Visit 12 (Hour 504/Day 21)
This visit will take place 504 hours (21 days) after the first dose. During this visit, the following activities will be completed:

- Blood draw **–** up to 10 mL (about 2 teaspoons)
- Collection of urine sample
- Swab collection done by participant – rectal, vaginal (if applicable) and throat

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 coordinator. 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. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may still be used for this study unless you specifically request the study team to destroy your samples.

What are the possible risks and discomforts?
Risks and discomforts related to the study include the following:

Sensitive Study Test Results
It is possible that you will find out that you have HIV, gonorrhea or chlamydia during this study. This could cause you some stress. Study staff will be available for counseling before and after your test, regardless of the results. Also, we will refer you to a medical provider for further care.

Blood Draw
Having your blood taken can cause discomfort. This discomfort is temporary but may cause lightheadedness or fainting. Taking blood can cause bruising. Bruising can be prevented or reduced by putting pressure on the site for a few minutes after the blood is taken. Rarely, some people get an infection where the needle was put in their arm to draw the blood. To reduce the risk of infection, we will wipe the area clean with alcohol and use sterile equipment.

Rectal Biopsy
Rectal biopsies may cause mild irritation and the sensation of needing to pass stool, as well as limited bleeding for 1 to 3 days after the procedure. Bowel puncture, infection and bleeding are extremely rare complications of this procedure and could need treatment with antibiotics and/or surgical repair. The risk of such difficulties is less than 1 in 5,000 each time the procedure is done. There is also risk of infection and death as a result of bowel puncture. There may be additional risks of the biopsy procedure, which are not known at this time. Bottoming (receptive anal intercourse) the week following the biopsies can increase your risk of sexually transmitted diseases including HIV.

Vaginal/Cervical Biopsy
Vaginal and cervical biopsies may cause mild pain, discomfort, and a persistent odor. In rare cases, persistent bleeding and infection may occur. You should refrain from having vaginal intercourse the week following this biopsy procedure as this can increase your risk of sexually transmitted diseases including HIV.

Doxycycline
Doxycycline is an FDA-approved drug used for treating infections caused by bacteria. The side effects of this drug are well known.

Common Side Effects
- Diarrhea

Less Common Side Effects
- Vomiting
- Nausea
- Dysphagia
- Allergic reaction

Rare Side Effects
- Liver toxicity

- Skin peeling
- Decreased kidney function
- Severe allergic reactions
- Decreased red blood cells
- Decreased white blood cells

If it is biologically possible for you to become pregnant: to protect against possible side effects of the study drug, people who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not fully understood. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant people will be taken out of the study.

When take the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?
You may not benefit from joining the study. This study is designed to learn more about how doxycycline taken by mouth is absorbed in the tissues of the rectum and vagina to see if it may be helpful for treating STIs. The study results may be used to help others in the future.

Will you be paid for your time and effort?
You will be compensated according to the schedule below:

- Screening Visit: $50
- In Clinic Follow-Up Visits: $50 x 10 visits = $500
- Biopsy Visit: $100 x 2 visits = $200
- Total Compensation: $750
- Unscheduled/Drug Dispensation Visit (if needed): $20

If you do not finish the study, you will compensated for the visits you have completed. You may also receive an additional $25 for peer referrals to the study if the peer referral enrolls in the study and identifies you as the referral source.

We are planning to provide compensation to you by a personal payment card. We issue this to you free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. You will be paid following each time you complete a visit. The card system is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card.

Emory University and Grady Health System is required by law to report any payments we make to the IRS. To do this, Emory University and Grady Health System Departments of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University and Grady Health System Departments of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during

this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card.

We would also like the option of compensating you in the form of cash, check or gift card if ClinCard accessibility is not available. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options. You will need to fill out a W-9 form.

What are your other options?
Participation in this study is voluntary. You may choose not to participate.

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
There is a Certificate of Confidentiality from the CDC for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory and Grady Health System will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory and Grady Health System received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory and Grady Health System from making the following disclosures about you:

- 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.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

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 take reasonable steps to keep copies of this form out of Emory's medical records system. If we aren't successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

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 and Grady Health System or elsewhere. We may share the data or specimens, linked by the study code, with other researchers at Emory and Grady Health System, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory and Grady Health System. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

We will use your specimens and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

Returning Results to Participants/Incidental Findings
We will return the results of the HIV/STI tests to you and help you get treatment if you test positive. However, in general, we will not give you any research test results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Future Use of Specimens
Leftover specimens may be stored for future research use in other research projects. You cannot participate in this protocol if you do not want your specimens stored for possible future use. Your name and personal identifying information will not be labeled on the stored specimens.

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 and Grady Health System will help you get immediate medical care. However, Emory, Grady Health System 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 discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

- It is not safe for you to have a biopsy procedure.
- Changes in your health or medications that make you ineligible for the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we may 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.

Purpose of this Authorization:

By signing this form, you give us permission to get your PHI from health care entities and to use and disclose your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment

There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or disclosed for the research study includes:

- 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.

Purposes for Which Your IIHI Will be Used/Disclosed:

We will use and disclose your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

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.

People Who will Use/Disclose Your IIHI:

The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory and Grady Health System may use and disclose your IIHI to run normal business operations.
- The Principal Investigator and research staff will disclose your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- The National Institutes of Health (NIH) is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results

of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- Greenphire

The following people and groups will use your IIHI to make sure the research is done correctly and safely:

- Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, the Emory Office for Clinical Research and the Grady Research Oversight Committee.
- Government agencies that regulate the research including: Office for Human Research Protections
- Public health agencies
- Research monitors and reviewer
- Accreditation agencies

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be disclosed to the new institution and the institution's oversight offices.

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:

[redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the IIHI already collected as described in this Authorization. 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 purposed. 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 [redacted] 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 [redacted] or [redacted] or [redacted]

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent

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 form to keep.

_____
Name of Subject

_____ _____ **am / pm**
Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ **am / pm**
Signature of Person Conducting Informed Consent Discussion **Date** **Time**

Optional Rectal Biopsies Information

Applicable only for people who have vaginas

Your data and/or specimens will be protected the same way as the data and/or specimens for the main study. There are no additional risks or costs for completing the optional rectal biopsy than the ones already described for the main study (see sections above).

What is the purpose of this optional rectal biopsies?
The purpose of the optional rectal biopsy is to collect extra tissue for the researchers to use. Collecting this tissue provides more information to answer the study question.

What will I be asked to do?
If you choose to take part in the optional rectal biopsies, you will have an additional rectal biopsy procedure at Visits 2 and 8. This optional rectal biopsy procedure is done the same way as described earlier in this document.

Will I benefit directly from the study?
The optional rectal biopsies are not designed to benefit you directly. This study is designed to learn more about how doxycycline is absorbed in the rectum. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
If you are a person with a vagina and you chose to have the optional, additional rectal biopsy, you will receive $100 for each procedure ($200 total if you complete both). Compensation for this procedure will also be provided via ClinCard.

What are my other options?
You can participate in the main study and not take part in the optional rectal biopsies.

Withdrawal from the Optional Rectal Biopsies
You have the right to decide not to do the optional rectal biopsies at any time without penalty. You may stay in the main study even if you decide not to do the optional rectal biopsies.

The researchers also have the right to stop your participation in the optional rectal biopsies without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- It is not safe for you to have a rectal biopsy procedure.

Contact Information
See contact information for the main study, above.

Consent

Please indicate below whether or not you agree to participant in the optional, additional rectal biopsies. Choose only **one** of the options below and initial beside your choice.

_____ YES, I agree to the collection of optional neovaginal samples.
(Initials)

_____ NO, I do not agree to the collection of optional neovaginal samples.
(Initials)

_____ Not applicable.
(Initials)

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below to confirm your selection above. By signing this form, you will not give up any of your legal rights. We will give you a copy of the form to keep.

_____
Name of Subject

_____ _____ **am / pm**
Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ **am / pm**
Signature of Person Conducting Informed Consent Discussion **Date** **Time**