CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Viamet Pharmaceuticals, Inc. / "A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of VT-1161 Oral Tablets in the Treatment of Patients with Recurrent Vulvovaginal Candidiasis"**
Protocol Number:	**VMT-VT-1161-CL-006**
Principal Investigator:	**Michael L. Twede, M.D., FACOG**
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Take as much time as you need to review this information and ask as many questions as you want. You should ask your study doctor about other treatments available for your condition.

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject.

INTRODUCTION

You are being asked to participate in a research study (experimental study) under the direction of the study doctor because you have been diagnosed with recurrent vulvovaginal candidiasis (VVC, sometimes called a "yeast infection"). The VVC is called recurrent because the infection went away with treatment, but came back at least 3 times in the past year. You will be one of approximately 200 subjects taking part in this research study. Your participation in this research study will last for approximately 50 weeks.

The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits.
- Parts of this study involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study involve experimental (investigational) drugs or procedures that are being tested for a certain condition or illness. An investigational drug is one that has not been approved by the U.S. Food & Drug Administration (FDA).
- After reading the consent form and having a discussion with the study staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study. However, your health information will remain protected at all times.
- You will not be charged for additional tests or procedures done solely for research purposes. The sponsor of this study, Viamet Pharmaceuticals, may provide reimbursement for expenses related to study participation which are submitted but declined by your health insurance provider.
- Any standard medical care you receive during the research study should be addressed through your normal medical insurance.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE RESEARCH STUDY

The purpose of this research study is to determine whether the study drug is safe and effective in controlling recurring vaginal yeast infections. The study drug, VT-1161, is an experimental drug, to be taken by swallowing two tablets, that has not yet been approved by the United States Food and Drug Administration for use by the public. VT-1161 has been designed to stop the growth of the yeast which is often responsible for causing the vaginal infection with which you have been diagnosed. VT-1161 has also been designed to have fewer side-effects and work with fewer doses than other medications typically used to treat recurrent yeast infections.

Description of the Research study

During this research study, you will first receive study treatment with fluconazole. Fluconazole is an approved treatment for vaginal yeast infection, and is a pill taken by mouth. Then, if your yeast infection goes away and you continue to qualify for the study (i.e., meet certain criteria), two weeks later you will be randomly chosen (like flipping a coin or pulling a number from a hat) to either receive the study drug, VT-1161, or a placebo. A placebo is a product that is made to look like the study drug, but contains no medication. You will have a 1 in 5 chance of receiving a placebo during the research study. You and your study doctor will not know if you are receiving the study drug or a placebo (this is called a blinded study). However, the identity of your study treatment may be made available to your study doctor in the event of a medical emergency.

Pharmacokinetics (PK)

This study will also look at the pharmacokinetics of the study drug. Pharmacokinetics looks at how your body:

- Takes the study drug into the blood.
- Delivers the study drug through the blood.
- Breaks down or processes the study drug.
- Removes the study drug.

PROCEDURES

Initial (Screening) Visit

At the initial visit, your study doctor will explain the purpose of the study and, through this form, will ask you to provide your permission to be included in the study. You will also be asked to permit the disclosure of protected health information for the purposes of confirming your eligibility for the study and study drug evaluation. After these steps, you will be screened to determine if you are a good fit for this study. At the screening visit, you will be asked about your medical and surgical history, alcohol and cigarette use, the medications you have taken within 30 days before this visit (including prescription and non-prescription medication, vitamins, and herbal medications) and any non-drug treatments (*e.g.*, douches, sitz baths) within the last 72 hours. Additionally, the following tests will occur:

- A physical exam, including a vaginal exam with a speculum (similar to an annual exam done by your gynecologist).
- Measurements of your temperature, blood pressure, heart rate, breathing rate (your vital signs), height and weight will be recorded.
- An electrocardiogram (ECG) will be performed. An ECG measures the electrical activity of your heart.
- There will be a urine test to look for abnormalities and to test if you are pregnant.
- You will be screened for chlamydia, gonorrhea, trichomoniasis and HIV (sexually transmitted infections).
    - State law requires that the results of positive tests for HIV be reported to a local health agency.
- A blood test will be performed to look at your red and white blood cells, your liver and kidney functions, your blood chemistry levels, and to test if you are pregnant. The total amount of blood taken during this visit will be approximately 1 tablespoon (15 mL). The blood test will also test for hepatitis B, and hepatitis C.
    - State law requires that the results of positive tests for Hepatitis be reported to a local health agency.
- A sample of vaginal fluid will be collected to confirm that you have a yeast infection and that you don't have some other kind of vaginal infection.

Induction Visit

The Induction period is the time when you will receive study treatment with fluconazole. If you are eligible for this study at the screening visit, you can start fluconazole on the same day as the Screening Visit.

If your Screening Visit and Induction Visit are not on the same day, you will come back to the clinic within 3 days and will be asked about any medications and non-drug treatments you have taken since the screening visit. Your temperature, blood pressure, heart rate, and breathing rate (your vital signs) will be taken and you will receive the first of 3 doses of fluconazole.

You will be given two more doses to take at home. The second and third doses of fluconazole should be taken at approximately the same time of day as the first dose; 3 days and 6 days after the first dose of fluconazole. You will also be instructed not to have sex until after you return to the clinic for your next visit.

Study Treatment and Follow-up Visits

You will return to the clinic 14 days (+/- 4 days) after the Induction Visit. Some additional assessments will be completed to determine if you are still a good fit for the study. This visit is called Day 1, because it is the day you may start the study drug.

Day 1 Visit

The following procedures will be performed on Day 1:

- Any medications or other treatments you have taken will be written down.
- Adverse events (unwanted symptoms that may or may not be side effects of the study drug) will be written down.
- Temperature, blood pressure, heart rate, and breathing rate (your vital signs) will be measured.
- A vaginal examination with a speculum (similar to an annual exam) and a physical examination will be performed.
- A sample of vaginal fluid will be collected to test for yeast infection.
- An electrocardiogram (ECG) will be performed to measure the electrical activity of your heart.

- A blood sample (about 1 tablespoon (15 mL) will be taken before you receive the study drug. A blood test will be performed to measure your red and white blood cells, your liver and kidney functions, and your blood chemistry levels.
- A urine sample will be taken to look for abnormalities and to test if you are pregnant.
- You will be randomly assigned to a study group and will receive either VT-1161 or placebo and will be given the first dose within 30 minutes of eating a meal at the clinic.
- You will be given study drug to take at home and instructed to take 2 tablets with a cup of water once daily on Days 1 through 7 within 30 minutes of eating your main meal of the day. The study drug should be taken at approximately the same time of the day, throughout the study.

Day 7 (±2 days)

You will be asked to return to the study site for the following follow-up tests on Day 7. You should bring your used study drug card with you. If you choose to participate in the serial PK sampling you should not take your study drug dose at home but bring the study drug card with you to take that dose during the visit.

- Any medications or other treatments you have taken will be written down.
- Adverse events (unwanted symptoms that may or may not be side effects of the study drug) will be written down.
- Temperature, blood pressure, heart rate, and breathing rate (your vital signs) will be measured.
- A vaginal examination with a speculum (similar to an annual exam) and a physical examination will be performed.
- An electrocardiogram (ECG) will be performed to measure the electrical activity of your heart.
- A urine sample will be taken to look for abnormalities.
- A blood sample (about 1 tablespoon (15 mL)) will be taken before you receive your dose of study drug for the day. A blood test will be performed to measure levels of study drug in your blood and to measure your red and white blood cells, your liver and kidney functions, and your blood chemistry levels.

- Optional Serial PK sampling: You will be given the choice of providing additional blood samples. If you agree to participate, you'll be given a meal, and blood samples will be taken 1, 2, 3, 4, 5, 6, and 8 hours after you take the study drug in the clinic to measure the levels of study drug in your blood. The amount of blood taken for the additional samples will be approximately 1.5 tablespoons (21 mL). There is a place at the end of this form for you to indicate your choice of whether to take part in this optional serial PK sample collection.
- The study staff will review the used study drug card that you've brought with you to the visit.
- You will be given study drug to take at home and instructed to take 2 tablets with a cup of water once weekly starting on Day 8 through Week 24, within 30 minutes of eating your main meal of the day, at approximately the same time of the day, throughout the study.

Week 4 (± 4 days) and Week 8 (±4 days) Visits

You will be asked to return to the study site at Week 4 and Week 8 for the following follow-up tests. You should bring your used study drug card with you.

- Any medications or other treatments you have taken will be written down.
- Adverse events (unwanted symptoms that may or may not be side effects of the study drug) will be written down.
- Temperature, blood pressure, heart rate, and breathing rate (your vital signs) will be measured.
- A vaginal examination with a speculum (similar to an annual exam) and a physical examination will be performed.
- A sample of vaginal fluid will be collected to test for yeast infection.
- A blood test will be performed to measure levels of study drug in your blood and to measure your red and white blood cells, your liver and kidney functions, and your blood chemistry levels. The total amount of blood taken during this visit will be about 1 tablespoon (15 mL).
- A urine sample will be taken to look for abnormalities.
- The study staff will review the used study drug card that you've brought with you to the visit.

Week 12 (±7 days) Visit

You will be asked to return to the study site at Week 12. You should bring your used study drug card with you. At this visit, the following tests will be performed:

- Any medications or other treatments you have taken will be written down.
- Adverse events (unwanted symptoms that may or may not be side effects of the study drug) will be written down.
- Your weight will be recorded.
- Temperature, blood pressure, heart rate, and breathing rate (your vital signs) will be measured.
- A vaginal examination with a speculum (similar to an annual exam) and a physical examination will be performed.
- A sample of vaginal fluid will be collected to test for yeast infection.
- An electrocardiogram (ECG) will be performed to measure the electrical activity of your heart.
- A blood test will be performed to measure levels of study drug in your blood, to measure your red and white blood cells, your liver and kidney functions, your blood chemistry levels and to test if you are pregnant. The total amount of blood taken during this visit will be about 1 tablespoon (15 mL).
- A urine sample will be taken to look for abnormalities.
- The study staff will review the used study drug card that you've brought with you to the visit.
- You'll be given study drug to take at home and instructed to take 2 tablets with a cup of water once weekly through Week 24, within 30 minutes of eating your main meal of the day, at approximately the same time of the day, throughout the study.

Week 18 (±7 days) Visit

You will be asked to return to the study site at Week 18. You should bring your used study drug card with you. At this visit, the same tests will be performed as during the Week 4 and Week 8 visits.

Week 24 (±14 days) Visit

You will be asked to return to the study site at Week 24. You should bring your used study drug card with you. At this visit, the same tests will be performed as during the Week 12 visit.

Week 30

The study staff will call you to remind you of your next appointment and to ask about any new adverse events you may have had (unwanted symptoms that may or may not be side effects of the study drug) and medications you've taken since your last visit.

Week 36 (±14 days) Visit

You will be asked to return to the study site at Week 36. At this visit, the same tests will be performed as during the Week 4, Week 8, and Week 18 visits.

Week 42

The clinic will call you to remind you of your next appointment and to ask about any new adverse events you may have had (unwanted symptoms that may or may not be side effects of the study drug) and medications you've taken since your last visit.

Week 48 (±14 days) Visit

You will be asked to return to the study site at Week 48. At this visit, the same tests will be performed as during the Week 12 and Week 24 visits.

After this visit, your participation in the study will be completed.

After you have completed participation in this study, the study doctor will evaluate your results and those of the other participants from the study, and return the findings to the sponsor, Viamet Pharmaceuticals, Inc. The sponsor will then evaluate the findings of the study.

Unscheduled Visits/Recurrent Episode

At any time during the study, if you think you have symptoms of a vaginal yeast infection you are to contact and return to the site to be diagnosed and treated. If for any reason you are not able to go to the site for evaluation and you seek medical care in an urgent care or other medical care facility, you are to mention that you are participating in this research study to allow for the appropriate collection of information. You will receive a subject card that will contain instructions as to the information that should be collected in such event.

RISKS AND DISCOMFORTS

As with any study drug, there may be risks that are not expected or foreseen.

Possible side effects of **fluconazole** include, but are not limited to, the following:

- Headache
- Increased levels of creatine kinase, a chemical in the blood, which could lead to muscle pain
- Increased levels of alanine transaminase (ALT) or aspartate transaminase (AST), these are chemical compounds found in the blood, which can indicate possible liver damage
- Upset stomach
- Mild stomach pain
- Nausea
- Heartburn
- Diarrhea
- Skin rash
- Dizziness
- Changes in the way food tastes

Rare, but serious possible side effects of fluconazole include:

- Fast/irregular heartbeat
- Severe dizziness
- Fainting
- Severe stomach pain
- Persistent nausea/vomiting
- Yellowing eyes/skin
- Dark urine
- Unusual tiredness

Possible side effects of **VT-1161** include, but are not limited to, the following:

- Back or muscle pain
- Headache
- Dizziness
- Nausea
- Skin Rash
- Increased levels of creatine kinase, a chemical in the blood, which could lead to muscle pain.
- Increased levels of alanine transaminase (ALT) or aspartate transaminase (AST), these are chemical compounds found in the blood, which can indicate possible liver damage

Allergic Reactions

While unlikely, it is possible that an allergic reaction to study drug (VT-1161) or fluconazole could occur. An allergic reaction could result in hives, skin rash, swelling of the eyelids, face, mouth, neck, or other body part, difficulty breathing, fever, chills, and throbbing of heart or ears. These reactions are usually reversible but in rare cases could lead to permanent disability or death.

In most cases the severity of side effects are mild and they will get better on their own. In some cases, subjects may require treatment from the study doctor. In very rare cases side effects may require hospitalization.

Risks of Blood Testing

Possible risks of taking blood (placement of a needle or tube into a blood vessel) include the following:

- Bruising
- Pain
- Irritation or perforation (hole) of the vein
- Bleeding
- Infection
- Fainting

Reproductive Risks

Because of unknown potential effects of the study drug to a fetus or child, you will be admitted into the study only if you agree to either abstain from sexual intercourse or if you use one of the following alternate methods of birth control:

- Surgically sterile (bilateral tubal ligation, hysterectomy, bilateral oophorectomy) for at least 6 months prior to the first dose of study drug.
- Intrauterine device (IUD) in place for at least 3 months prior to the first dose of study drug.
- Barrier methods (diaphragm plus spermicide or condom). (These barrier methods are prohibited from Day -14 through Day 1 of the study. Therefore two weeks prior to Day 1, the only method of birth control will be abstinence).
- Females who claim abstinence as their method of contraception are allowed study entry provided they agree to use a barrier method (diaphragm plus spermicide or condom) should they become sexually active after Baseline through 48 weeks. (These barrier methods are prohibited from Day -14 through Day 1 of the study. Therefore two weeks prior to Day 1, the only method of birth control will be abstinence).
- Surgical sterilization of the partner (vasectomy) for at least 6 months prior to the first dose of study drug.

- Hormonal contraceptives starting at least 3 months prior to the first dose of study drug. If hormonal contraceptives were started less than 3 months prior to the first dose of study drug, subjects must agree to use a barrier method (diaphragm plus spermicide or condom), through 3 months after the initiation of hormonal contraceptives. (Since these barrier methods are prohibited from Day -14 through Day 1 of the study, two weeks prior to Day 1, the only adjunctive method of birth control will be abstinence).

If you think that you have become pregnant during the study, you must tell your study doctor immediately.

Other Risks

Your condition may not get better or may get worse during this study. If this happens, you can receive other treatment for your yeast infection. Additionally, there may be side effects not known at this time.

Only you should take the study drug. It must be kept out of the reach of children or anyone else who may not be able to read or understand the label.

NEW INFORMATION

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

POTENTIAL BENEFITS

You may find that you have fewer or no additional yeast infections while you are in the study; however, this cannot be promised. Studies such as this also provide information that could help improve the treatment available for recurrent yeast infections in the future.

STUDY STAFF PAYMENT

Viamet Pharmaceuticals, Inc. is paying the study doctor and study staff for their work in this study.

COSTS

The study sponsor, Viamet Pharmaceuticals, will pay for the procedures, tests, and treatments performed for research purposes. The expense of any procedures, tests, or treatments related to your normal medical care will be billed to you or your insurer in the regular way.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

You will not be charged to participate in this research study.

COMPENSATION

You will be reimbursed for your participation in this research study. If you do not complete the study, you will be reimbursed only for the visits you have completed. Visits payments are noted below:

Screening Visit = $45.00

Induction Visit = $25.00

Day 1 = $45.00

Day 7 = $45.00

Weeks 4, 8, 12, & 18 = $45.00 per visit

Week 24 = $70.00

Telephone contact at Week 30 & 42 = $15.00 per phone call

Week 36 = $50.00

Week 48 = $70.00

Unscheduled visits for a recurrent yeast infection = $50.00 per visit

If you choose to participate in the optional serial PK sampling at Day 7, you will be compensated an additional $200.00 for your time.

You will be paid at each visit or at the end of your participation in the research study, whichever you prefer. Payment will be mailed via US Mail in the form of a check.

Taking part in this study may result in extra clinic visits and added costs to you. For example, you may need to pay for parking at the hospital/clinic or taxi fare to and from the clinic. Funds may be available to you from the Sponsor if this is a hardship for you. Please talk to your study doctor about this.

ALTERNATIVE TREATMENTS

If you decide not to take part in this study, there are other choices available for the treatment of acute VVC. These include drugs you can buy without a prescription,

such as vaginal suppositories (medication that dissolves in the vagina) or creams (miconazole, clotrimazole, butoconazole). Prescription cream (terconazole) or pills (fluconazole, itraconazole) are also available.

The length of the study treatment can range from one day to seven days. Ask the study doctor to discuss these alternative treatments with you. You do not need to be in the study to receive treatment for your yeast infection.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The document you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Name, address, telephone number or other facts that could identify the health information as yours.
- Past and present medical records (the past 5 years of your medical history will be reviewed for study eligibility)
- Information created or collected during the study
- Physical exam and laboratory test results done as part of this research study or as part of your regular care.
- Records about phone calls made as part of this study
- Records about your study visits.

All identifying information such as your name and address will be kept private. This information may be kept at this office or institution forever. Every attempt will be made to keep your information private. In some instances, in order to ensure the scientific value of the study, the parties named below will be able to view your study record but will not be permitted to copy any identifying information contained in your record.

Who may use and give out information about you?

In working with the sponsor, the study doctor and the study staff will use and share personal health information about you. In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor and its representatives may review or copy your personal health information at the study site.

"Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Who might get this information?

Your information may be given to the following groups to make sure that the study is done properly or for other purposes required by law:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Chesapeake IRB (a committee that reviews the ethics and safety of biomedical research studies)

In unusual cases, the study doctors may be required to release your medical record information in response to an order from a court of law. If the study doctors learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by law.

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

You do not have to sign this Authorization, but if you do not, then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

Yes, 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 doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

Publication and Redisclosure of Your Medical Record Information

If the results of this research study are published or presented, your identity will remain private.

After your medical record information from this study is disclosed, it may be redisclosed by the recipient and may no longer be protected by federal and state privacy laws. However, it will only be redisclosed for purposes approved by the local institutional review board or as required by law or regulation and may still be protected by other federal and state laws.

Expiration and Termination of Authorization to Use Your Medical Record Information

Your authorization for use and disclosure of your medical record information will continue indefinitely.

CLINICALTRIALS.GOV

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.

RESEARCH-RELATED INJURY

All forms of medical testing and treatment (both experimental and routine) involve some risk of injury. The study doctor will try to reduce the chances that you will experience discomfort or injury during this research study. In spite of all precautions, you may develop medical complications from participating in this research study.

In the case of research-related side effects or injury, medical care will be provided by your study doctor or you will be referred for appropriate medical care. Although no funds have been set aside to compensate you in the event of injury or illness related to the study drug or procedures, you do not waive your legal right to such compensation by signing this form.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THE RESEARCH STUDY

Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. The quality of your health care will not be affected.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not follow instructions;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- the study has stopped;
- or the study doctor's or sponsor's decision.

If you leave the study before the planned final visit, you will be asked by the study doctor to have some tests or procedures done so that you leave the study safely.

QUESTIONS REGARDING PARTICIPATION IN A RESEARCH STUDY

You can ask questions about this consent form or the study (before you decide to start the study or at any time during the study). Questions may include:

- Who to contact in the case of a research-related injury or illness.
- Any payment for being in the study.
- Your rights and your responsibilities as a study subject.
- Other questions.

Contact the study doctor or study staff with any questions or concerns. Their telephone number is printed on the first page of this form. If you have any questions or complaints about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00010601.

Optional Serial PK Sample Collections at Day 7 Visit

☐ I agree to participate in the optional serial PK sampling at the Day 7 Visit. In addition to a pre-dose blood sample, I agree that additional blood samples may be taken at hours 1, 2, 3, 4, 5, 6, and 8 after I take the study drug on Study Day 7.

☐ I decline to participate in the optional serial PK sampling at Day 7. You can still be in the main study if you do not agree to have the PK samples taken.

Your Consent to Participate in the Study and Authorization for Use and Disclosure of your Medical Record Information

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

You will be given a copy of the signed form for your records and continued reference. By signing this form, I have not given up any of my legal rights.

Subject name (printed)	Signature of subject	Date

I attest that I have explained the purpose, tests, procedures, benefits, and risks of this research study to the participant and the nature and purpose of the use and disclosure of identifiable medical record information. The subject has been given the opportunity to consider her options in response to the information provided. I verify that sufficient time has been allowed for questions and exchange of information.

Printed name of person conducting the informed consent discussion	Signature of person conducting the informed consent discussion	Date