CONSENT TO PARTICIPATE IN RESEARCH AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

**Study Title:** A Multicenter, Randomized, Double-Blind, Vehicle-Controlled Study Evaluating the Therapeutic Equivalence and Safety of GDC-229 (Investigational Metronidazole 0.75% Vaginal Gel) and Metronidazole 0.75% Vaginal Gel in the Treatment of Bacterial Vaginosis

**Study #:** GDC-229-002

**Sponsor:** Gage Development Company, LLC

**Study Doctor Name:** **Kelle S Oberle MD, FACOG**

**Research Site Address(es):**

|  |
| --- |
| Physicians Research Options Red Rocks ObGyn  255 Union Blvd Ste 200  Lakewood CO 80228 |

**Daytime Telephone Number(s):** 303-985-9100

**24-hour Contact Number(s):** 303-763-5111

**Subject Number:** |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|

**INTRODUCTION**

You are being asked to volunteer for a clinical research study (“Study”). Before you decide if you would like to be in this Study, it is important for you to understand why the Study is being done and what will happen to you while you are in the Study. This document provides information about the Study and your rights as a subject in this Study to help you decide if you want to be in this Study.

Please read this document carefully. You may discuss it with friends, family, or your own doctor, if you wish. Please ask the Study Doctor or Study staff if you have any questions. Take your time to decide whether or not you would like to be in this Study. If you agree to be in this Study, you will be asked to sign this consent form.

The Study is being paid for by Gage Development Company (“Sponsor”). The Study doctor is being paid by Gage to do this Study.

You must be honest with the Study Doctor when you are asked questions about your health.

If you do not understand this document, please ask the Study Doctor or the Study staff to explain any words or information that you do not understand.

**WHY IS THIS STUDY BEING DONE?**

You are being asked to be in this research Study because you may have an infection of the vagina called bacterial vaginosis (BV). BV is a common vaginal infection in women caused by too much bacteria. You may have thin white or gray vaginal discharge, bad-smelling vaginal odor, or itching and burning when you urinate. However, you may not have any of these problems. You will be examined to see if you have any vaginal discharge and the Study staff will do laboratory tests to see if you have BV.

Antibiotics (drugs that kill bacterial infections) are used to treat BV. Metronidazole vaginal gel is an FDA-approved antibiotic that is used for the treatment of BV. The investigational antibiotic (Study medicine) that is being tested in this clinical research trial is a generic form of the FDA approved metronidazole vaginal gel. A generic medicine is a medicine that is identical to the brand medicine in the ingredients, dose, and the way in which it is administered. The purpose of this clinical research Study is to find out if the generic metronidazole vaginal gel is as safe and works as well as the FDA-approved metronidazole vaginal gel.

**HOW MANY SUBJECTS ARE IN THIS STUDY?**

Around 738 women 18 years of age or older will be enrolled into this Study at around 40 sites in the United States.

**HOW LONG IS THE STUDY?**

You will be in this Study for about one month. You will have three (3) visits to the Study center: Entry Visit (Visit 1; Day 1), Visit 2 (7 to 14 days after Entry Visit), and Visit 3 (21 to 30 days after Entry Visit).

**WHAT MEDICINES WILL I BE GIVEN IN THIS STUDY?**

If the Study Doctor decides you should be in this Study and if you agree to be in this Study, you will be randomly assigned by chance to receive one of the following Study medications:

* FDA-approved Metronidazole Vaginal Gel (0.75%)
* Investigational Study drug (generic Metronidazole Vaginal Gel (0.75%)
* Placebo (gel that does not contain any medicine)

You have a one in three chance of being assigned to each Study medication (like drawing straws). You will use the medicine every night at bedtime, for five straight nights. Each daily dose will be five grams (about one teaspoon) of medication. You will place the medicine into the plastic applicator and insert the applicator into your vagina to administer the medicine. You will not know if you are using the FDA approved medicine or the generic medicine or the placebo. You will receive the same Study medication during the whole Study. If there is an emergency, your Study Doctor can find out which medicine you are taking.

**HOW WILL THE STUDY DOCTOR DECIDE IF YOU CAN BE IN THIS STUDY?**

You must be healthy to be in this Study.

You cannot be in this Study if you:

* Are not using an acceptable method of birth control (see the Birth Control and Sexual Intercourse Restrictions section below for information)
* Have a current or recent history of alcohol or substance abuse
* Have another sexually transmitted illness or another vaginal infection besides bacterial vaginosis
* Have had an important medical event in the past 90 days (for example, stroke, surgery)
* Have a history of any central nervous system (CNS) diseases
* Have had an abnormal pap smear, or if you have been seen or treated for high risk human papilloma virus (HPV) within the last three months
* Are being treated, or will be treated, for cervical cancer or pre-cancerous growths while in this Study
* Are in another research Study, or were in any other research Study within the last 30 days
* Are taking any drugs of abuse (illegal street drugs and/or prescription). Your urine will be tested for these drugs.
* Have your period at the first visit
* Are pregnant or breastfeeding your baby
* Have an allergy to metronidazole, parabens, and/or nitroimidazole products
* Are taking or have taken any of the following drugs within the past two weeks:
  + Disulfiram
  + Lithium
  + Antibiotics
  + Antifungals
  + Anticoagulants
  + Cimetidine
* Have had vaginal therapy in the past two weeks or plans to during the Study
* You must not have used any products in your vagina within the past 48 hours, such as spermicides (including condoms with spermicidal lubricants), douches, tampons, feminine sprays, diaphragm or vaginal ring birth control.

**WHAT AM I REQUIRED TO DO TO BE IN THIS STUDY?**

While you are in the Study, you will need to:

* Be willing and able to follow the Study directions and procedures
* Tell the Study staff about any side effects or problems
* Ask questions as you think of them
* Tell the Study Doctor or the Study staff if you change your mind about staying in the Study
* Agree to not have sexual intercourse for five days while you are using the Study medicine and for an extra two days after you have finished using the Study medicine (Days 1-7 of the study). You also agree to not have sex for 48 hours before your scheduled Visit 2 and Visit 3.
* Agree not to drink alcohol for the first six days of this Study.
* Agree not to use any products or medicines in your vagina including spermicides, tampons, douches, feminine deodorant sprays, diaphragms, vaginal ring birth control, condoms with spermicide, and any vaginal drugs throughout the duration of the Study.
* Contact the Study staff if your period happens or is likely to happen at the same time as a visit to see the Study Doctor, so you can be given a new visit date. You should not be having your period when you come to see the Study Doctor for a visit.

**WHAT WILL HAPPEN DURING THE STUDY**

**Study Visits and Procedures**

**Entry Visit (Visit 1; Day 1)**

If you agree to participate, you will be asked to read and sign this informed consent document. After it has been signed, you will be given a copy to keep.

The first visit to see if you will be allowed to be in the Study is called the screening visit. This visit may take up to 2 hours and 30 minutes of your time.

During this visit:

* You will be asked to tell the Study Doctor about yourself, your health, your medical history (including gynecologic, menstrual, and sexual history), and all medicines and vitamins (prescription or over-the-counter) that you have taken for the last 30 days.
* Your height, weight, and vital signs (body temperature, blood pressure, heart rate, and breathing rate) will be measured.
* A urine pregnancy test will be done.
* A urine drug screen will be done.
* You will have a physical exam and a pelvic exam.
* Many samples from your vagina will be taken to test for sexually transmitted illnesses and to make sure that you have BV. Certain sexually transmitted diseases must be reported to the State health authorities who track sexually transmitted infection rates in the US population. If you test positive for one of these, the study doctor will follow the state/local laws for reporting.
* If the Study Doctor decides you can be in the Study and you agree to participate, you will be assigned by chance to medication (either metronidazole vaginal gel or placebo) and be given a 5-day supply of Study medicine to take home. You will also be given written instructions on how to use the medicine at home.
* You will be told to use the medicine every night before bedtime for five days in a row. You must begin using your medicine on the same day that you are given your medicine.
* You will be given an appointment to come back to the Study office for Visit 2. This visit should happen on a day that you do not have your period. The Study staff will ask you questions about your period so they can make your next appointment.

**Visit 2 (Day 7-14 after Visit 1)**

This visit may take up to 1 hour and thirty minutes of your time.

During this visit:

* You will be asked about your health and all medicines (including over the counter medicines) and vitamins you have taken since your last visit.
* You will be asked if you have noticed anything different in or around your vagina.
* Your vital signs (body temperature, blood pressure, heart rate, and breathing rate) will be measured.
* A urine pregnancy test will be done.
* You will have a pelvic exam.
* Many samples from your vagina will be taken to test for infection.
* You will return the tube (with any remaining Study medication) that you were given at Visit 1. You will also return the dosing instruction sheet and all unused medicine applicators.
* You will be given an appointment to come back to the Study office for Visit 3. Visit 3 will also happen on a day you do not have your period.

**Visit 3 (Day 21-30 after Visit 1)**

This visit may take up to one hour and thirty minutes of your time.

During this visit:

* You will be asked about your health and medicines (including over the counter medicines) and vitamins you have taken.
* You will be asked if you have noticed anything different in or around your vagina.
* Your weight and vital signs (body temperature, blood pressure, heart rate, and breathing rate) will be measured.
* A urine pregnancy test will be done.
* You will have a physical exam and a pelvic exam.
* Many samples from your vagina will be taken to test for infection.

**Early Termination Visit**

If you stop using the Study medicine early, or decide at any time that you do not want to be in the Study anymore, you will be asked to come to the Study office so that the doctor can examine you. You will have the Visit 3 procedures performed. You will be asked to bring back all of the medicine and all of the applicators that you did not use.

**POSSIBLE RISKS AND SIDE EFFECTS**

You must tell the Study Doctor or Study staff about all side effects that you have. Some side effects, if they are very bad, can be life-threatening. If you are not honest about your side effects, you may harm yourself by staying in this Study.

All drugs may cause side effects in some people. Below is a list of the most common side effects of metronidazole vaginal gel.

* Vaginal discharge
* Vaginal irritation or inflammation (may be a yeast infection) Upset stomach

Below is a list of less common side effects of metronidazole vaginal gel:

* Pain in your pelvis
* Headache
* Nausea
* Vomiting
* Unusual taste
* Dizziness

Below is a list of very unusual side effects of metronidazole vaginal gel:

* Diarrhea/loose stools
* Loss of appetite
* Bloated stomach or gas
* Feeling thirsty/dry mouth
* Feeling depressed
* Itching or rash all over your body
* Cramping
* Feeling tired
* Dark urine
* An increase or decrease in white blood cell counts, which could mean you have an infection or could be getting an infection.
* Convulsive seizures
* Feeling numb, burning or tingling in your arms or legs
* Psychotic reactions if you also taking disulfiram (Antabuse®)

People with liver disease, who are alcoholics, and/or who have other vaginal infections might have more side effects from metronidazole than other women.

Since metronidazole can make you dizzy, you should be careful with stairs, driving a car or working with machinery while you are taking this medicine.

All drugs may cause allergic reactions in some people. These are signs you might have an allergic reaction to metronidazole:

* Swelling of the face, lips, throat, and other areas of the skin
* Difficulty swallowing or breathing
* Raised, red areas on your skin
* Skin rash, itching, flaking, or peeling

If you do not understand what any of these side effects mean, please ask the Study Doctor or Study staff to explain these terms to you.

If you have any side effects of the Study medicine, please notify your Study Doctor immediately.

**Warning to Not Use Alcohol during Treatment for this Study**

It is important that you do not drink alcohol during the first six days of this Study. The first six days are all of the days you are using the Study medicine and one day after you are done using the Study medicine. .If you drink alcohol during any of these 6 days, you could become very sick.

**Other Risks and Discomforts in the Study**

* If you receive placebo, your infection will not be treated with active medicine, and may become worse, stay the same, or get better.
* Some women feel uncomfortable pressure when the samples from their vagina are taken.
* Some women feel uncomfortable from the pressure when the vagina is examined with a speculum.
* Some women have temporary spotting or bleeding after the exam.
* Some of the questions you will be asked may seem very personal or embarrassing.

**Unknown Risks**

There may be other risks that are unknown at this time. If new information about the safety of this drug becomes known while you are in the Study, and which could affect your decision to stay in this Study, the Study Doctor will let you know.

**BIRTH CONTROL AND SEXUAL INTERCOURSE RESTRICTIONS**

The Study Doctor will ask you questions to find out if you are of childbearing potential. You are not of childbearing potential:

* If you are over the age of 50 and have not had a period for over a year; or
* If you have had your tubes tied or have had your ovaries removed; or
* If you have been permanently sterilized (for example, if you had the Essure® procedure) at least 3 months before your first dose in this Study.

Taking the Study drug may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby), or nursing infant. Therefore, if you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot be in this Study. The only certain way to not get pregnant is to not have sex during the entire Study and for 14 days after the Study. If you choose to have sex, you must use birth control during the entire Study. The Study Doctor will tell you the type of birth control that you can use during the Study.

Acceptable forms of birth control include:

* Oral contraceptives (“the pill”) or transdermal contraceptives (“the patch”) must have been in use for at least one full menstrual cycle before you join the Study
* Intrauterine devices (IUDs), must have been inserted at least seven days before you join the Study.
* Contraceptive implants under the skin (e.g. Nexplanon) or injections (e.g. Depo-Provera) must have been implanted/inserted at least seven days before you join the Study
* Condoms without spermicide.

You may not use spermicides (including condoms with spermicide) at any time during this Study.

Even if you use birth control during the Study, there is a chance you could become pregnant. A pregnancy test could be wrong, especially if it early in the pregnancy. Tell the Study Doctor if you become pregnant or think you are pregnant. You can no longer be in the Study if you become pregnant. The study doctor would like to follow your pregnancy through the outcome and the baby through the first 8 weeks of life.

You must not have sexual intercourse during the 5 days that you are using the Study medicine and for two days after you have finished using the Study medicine (Days 1-7). You must also not have sexual intercourse for 48 hours before Visits 2 and 3.

You cannot be in the Study if you are breastfeeding. It is not known whether the Study medicine is safe for babies who are breastfeeding. You must tell the Study Doctor if you are breastfeeding or planning to breastfeed during the Study.

**OTHER STUDY RESTRICTIONS**

You may not use any products in your vagina other than the Study medicine for the whole time you are in the Study (Day 1 through your last Study visit). These products include: spermicides, tampons, douches, feminine deodorant sprays, diaphragms, vaginal ring birth control, condoms with spermicide, and any drug that is inserted into the vagina (such as Monistat, etc.). You also must not use any vaginal product that is rubbed onto the skin such as hydrocortisone while you are in this Study.

**BENEFITS**

Your BV infection may go away by being in this Study and taking the medicine as instructed. However, it is possible that you may not have any benefit from being in this Study. Other people, in the future, may benefit from the information learned from this Study.

**ALTERNATIVE TREATMENT**

You do not have to participate in this Study to receive treatment for your vaginal infection. If you choose not to be in this Study, there are other medicines available to treat your vaginal infection. You may receive metronidazole that is approved for marketing.

**FINANCIAL INCENTIVE**

You will receive $75.00 for your time and travel for each completed Study visit. You will be paid upon the completion of the study.

**COSTS**

You or your insurance company will not be charged for your being in this Study. The Study medicine, Study-related procedures and exams listed in this form will be provided to you at no charge to you or your insurance company. You will still be responsible for the cost of any other treatments, medicine, or procedures you receive as part of your regular care. You will not be reimbursed for any extra or follow-up testing which is not a part of this Study.

**COMPENSATION FOR INJURY**

If you become ill or are injured as a direct result of this research Study, medical treatment will be provided. Reimbursement for treatment not covered by your insurance may be provided in circumstances where the Sponsor and your Study Doctor determine the cause of the injury or illness is directly related to administration of Study medication or a Study procedure conducted in accordance with the Study protocol (the instructions on how to conduct the Study). The Sponsor will not pay for medical expenses related to extra or follow-up diagnostic testing (as described in the “Costs” section of this form) or to treat injuries that are not the direct result of the Study medication or a Study procedure, and which may be the result of an existing disease or treatment, your failure to follow the directions of the Study Doctor, and/or acts of the Study Doctor or Study staff that violated the law or the written Study protocol. Financial compensation for lost wages, disability, pain, or discomfort is not routinely available.

Sponsor has no plans to provide compensation other than that described above.

You will not lose any of your legal rights or release the Sponsor, the Study Doctor, the Study staff, or Study site from liability for mistakes or intentional misconduct by signing this consent document.

If you have questions, concerns, or complaints about this Study or to report a Study-related injury, contact the study doctor at the phone number(s) listed on page one of this form.

If you feel this emergency may be life-threatening, call 911.

**If you are unable to reach anyone at the number(s) listed above and you require immediate (life threatening) medical attention, please go to the nearest emergency room.**

**PRIVACY AND CONFIDENTIALITY**

Your Study Doctor and his or her staff will collect information about you. This information, called data, will be entered, without your name, on a report form. On all of those report forms, a code number will replace your name, so your name is not used. Your initials may also be used to identify you. All the data collected will be kept confidential. Authorized personnel will enter the data into the sponsor’s computer database. The data might be transferred to other sponsor locations within the United States or other countries for review or analysis by authorized personnel, but only for the purposes of the Study. Records of your participation in this Study will be held confidential except as disclosure is required by law or as described in this informed consent document (under "Confidentiality" or "Authorization to Use and Disclose Protected Health Information"). The Study Doctor, the company paying for the study and under certain circumstances, the United States Food and Drug Administration (FDA) and Copernicus Group Independent Review Board (CGIRB) (A group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects) will be able to inspect and copy confidential Study-related records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this Study are published or presented at meetings, you will not be identified.

In addition, information that does not identify you collected during this Study may be added to research databases and used in the future by the Sponsor and its agents to further study the Study medicine in future research and to study other medications or treatments.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this Study is voluntary and you may decide to quit at any time for any reason. Your decision not to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you agree to be in the Study, you may quit the Study at any time without penalty or loss of benefits. You may also withdraw your authorization allowing use of your personal information. However, data that has already been collected cannot be withdrawn.

If you decide to stop participating in the Study, alternative treatments for your condition will remain available to you. Your Study Doctor will ask you to complete the final visit assessments upon leaving the Study.

**WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The Study Doctor may stop your participation at any time without your consent if continuing in the Study does not appear to be in your best medical interest, if side effects or any other illness warrants discontinuation, if you fail to follow directions for participating in the Study, if it is discovered that you do not meet the Study requirements, if you are unable to follow the requirements of the Study, or if at any time the Sponsor, IRB, or the FDA decides to stop the Study.

If the Study Doctor withdraws you from the Study, or if you decide to withdraw from the Study, the following steps must be taken: (a) you must notify the Study Doctor, (b) you should return to the Study Doctor for a final examination (the Study staff will work with you to schedule this visit) and (c) you must return all of the unused Study medicine along with all unused applicators and the dosing instruction sheet.

If you withdraw from the Study or are discontinued before your Study completion, a member of the clinic’s staff may contact you to evaluate your health status.

**NEW FINDINGS**

During the course of this Study, you will be informed of any significant new findings (either good or bad) that might cause you to change your mind to continue participating. This information can include changes in the risks or benefits resulting from participation in the research or new alternatives to participation in the Study. If significant new information is provided to you, your written consent to continue participating in this Study will be obtained again.

**CLINICAL TRIAL INFORMATION**

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.

**CONTACT FOR INFORMATION AND EMERGENCIES**

If you have any questions, concerns, or complaints about your participation in this Study, or if at any time you feel you have experienced a research-related injury or a reaction to the Study medication, contact the Study doctor listed on page one of this informed consent.

**RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your consent at any time and discontinue your participation without any penalty. You are not waiving any legal claims, rights or remedies because of your participation in this Study.

This research is being overseen by an Institutional Review Board (“IRB”). You may talk to them at (888)-303-2224, irb@cgirb.com if:

* You have questions, concerns, or complaints that are not being answered by the research team.
* You are not getting answers from the research team.
* You cannot reach the research team.
* You want to talk to someone else about the research.
* You have questions about your rights as a research subject.

**PARTICIPANT’S STATEMENT OF CONSENT:**

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I voluntarily agree to participate in this Study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

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**Subject Signature Date/Time (HH:MM)**

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**Subject's Printed Name**

**STATEMENT OF PERSON CONDUCTING THE INFORMED CONSENT DISCUSSION:**

I have explained to the subject in language she understood the procedures to be followed in this Study and the risks and benefits involved.

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**Signature of Person Conducting the Consent Date/Time (HH:MM)**

**Discussion**

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**Printed Name of Person Conducting the Consent**

**Discussion**

***Please keep a copy of this document for your records.***

AUTHORIZATION TO USE AND DISCLOSE

PROTECTED HEALTH INFORMATION

During your participation in this Study, the Study investigatorand Study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the Study) and record it on Study documents. The Study Doctor will keep this personal health information in your Study-related records (that we will refer to as "your Study records"). In addition, the Study Doctor may obtain, and include in your records, information regarding your past, present and/or future physical or mental health and/or condition. Your Study Doctor may ask you to sign a separate authorization to obtain some or all of your medical records from your doctor. Your Study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research Study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." Therefore, you may not participate in this Study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the Study Doctor and staff to use your PHI to conduct this Study.

By signing this Authorization, you also are agreeing to allow the Study Doctor to disclose PHI as described below:

* The company paying for this Study and anyone working on behalf of the company to conduct this Study (referred to as "the sponsor"). The sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The Study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the sponsor. The sponsor may, however, look at your complete Study records that identify you. In addition, the sponsor may visit the Study site to oversee the way the Study is being conducted and may review your PHI during these visits to make sure the information is correct.
* Copernicus Group Independent Review Board (CGIRB) may have access to your PHI in relation to its responsibilities as an Institutional Review Board.

The Study Doctor or Sponsor may disclose your PHI to the United States Food and Drug Administration (“FDA”) or similar regulatory agencies or health authorities in the United States and/or foreign countries and Sponsor’s related companies in the US and in other countries.

These disclosures also help ensure that the information related to the Study is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here, although other safeguards apply. Please refer to the “Privacy and Confidentiality” section in the informed consent form to see how Sponsor will treat your PHI confidentially. If you have questions about how your PHI will be protected, you can ask the Study Doctor.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some or your entire PHI until the Sponsor has completed all work related to this Study in order to protect the integrity of the Study. At that time, you may ask to see your records.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin, this authorization will expire on 31Dec2060.

There is no expiration of this authorization except for research conducted in the states listed above.

You have a right to withdraw your Authorization at any time. If you withdraw it, your PHI will no longer be used for this Study, except to the extent the parties to the Study have already taken action based upon your Authorization or need the information to complete analysis and reports for the Study. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study. To revoke your Authorization, you must write to the Study Doctor, stating that you are withdrawing your Authorization to Use and Disclose Protected Health Information. If you withdraw this Authorization, you will not be allowed to continue to be in this Study.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

You will receive a copy of this Authorization after you have signed it.

**AUTHORIZATION**

By signing this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Subject Signature Date /Time (HH:MM)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of Subject**

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**Person Obtaining Authorization Signature Date /Time (HH:MM)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of Person Obtaining Authorization**