IRB APPROVED
AS MODIFIED
Apr 21, 2020

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Open-Label, Non-Randomized Study to Evaluate Anti-Malarial/Anti-Infective Combination Therapies in Patients with Confirmed COVID-19 Infection
PROTOCOL NO.:	HRI-COVID-19-Anti-Malarial-001 WIRB® Protocol #20200925 HonorHealth IRB# 1591056
SPONSOR:	HonorHealth
INVESTIGATOR:	Michael Gordon, MD 10510 North 92nd Street Scottsdale, Arizona 85258 USA
STUDY-RELATED PHONE NUMBER(S):	Michael Gordon, MD 480-323-1350 (24 hours)

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. If you are a legally authorized representative, please remember that "you" means the research (study) subject.

INTRODUCTION

You are being asked to take part in a clinical trial, a type of research study. Your participation is entirely voluntary. To allow you to make an informed decision as to whether you want to take part in this research study, this document describes the purpose of the study, your rights and obligations, the procedures needed by the study, and the possible benefits and risks of participating. You should read all of this information carefully and discuss your questions and concerns with your study doctor or healthcare team. You may take home an unsigned copy of this consent form to think about or discuss your decision with your family, friends and anyone you choose. You should not join this research study until all of your questions are answered. 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.

Clinical trials include only people who choose to take part. Please take your time to make your decision. If you have any questions, you can ask your study doctor for more explanation about the clinical trial, this form, or your disease. This consent form may contain words that you do

not understand. Please ask the study doctor or study staff to explain any words or information that you do not understand.

You are being asked to participate in a research study of two (2) drugs called atovaquone and azithromycin for the treatment of COVID-19 infection caused by the Severe Acute Respiratory Syndrome coronavirus-2 (SARS-CoV-2). Atovaquone and azithromycin has not been approved for the use described in this study by the Food and Drug Administration (FDA). However, the two drugs have been approved separately by FDA for other medical conditions, atovaquone under the trade name Mepron® and azithromycin under the name Zithromax®.

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. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study involve an experimental (investigational) drug that is 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 research 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.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

PURPOSE OF THE STUDY

The research is being done to see if the combination of atovaquone and azithromycin is safe and works in patients with COVID-19 infection. The research includes taking a twice daily dose of atovaquone and a once daily dose of azithromycin by mouth, check on your heart function and laboratory tests to check how your body responds to the drug combination. Atovaquone comes as a suspension (liquid) for administration by mouth and azithromycin comes as a tablet for administration by mouth. In the event you may not be able to take the azithromycin tablet by mouth, the dose may be administered crushed, mixed in water and given by mouth. You will receive investigational drugs atovaquone and azithromycin for up to 10 days and procedures will

be performed while you are admitted in the hospital for at least 10 days from when you enter the study after consenting to participate.

Who can participate in this study?
Up to twenty-eight (28), male or female 18 years of age or older who has a COVID-19 positive test result may participate. Pregnant or breastfeeding individuals cannot participate. If you are a female of childbearing potential, you will be tested for pregnancy. If you are pregnant or breastfeeding, you cannot participate.

PROCEDURES
After you or your Legally Authorized Representative agree to participate in the study you will be asked to complete the following:

Screening Visit:
Standard Procedures include:

- You will be asked about your medical history and medications you are currently taking
- You will be asked about how you are feeling and how you have been feeling in the prior 14 days
- Your treating physician will perform a physical examination
- Your blood pressure, temperature, pulse, respiration, height and weight will be taken
- Blood (1-2 teaspoons) will be collected to check your blood counts and organ function
- Blood (1-2 teaspoons) will be collected to check on COVID-19 antibodies and how your immune system is doing
- An electrocardiogram will be performed
- A chest X-ray may be needed, if you haven't had one in the prior couple of days
- Urine will be collected to check your kidney function
- Blood and/or sputum specimens may be collected if your treating physician needs to run cultures

Non-Standard Procedures:

- Blood will be collected for study-related analyses which are not related to your clinical care (about 1-2 teaspoons each sample)
- Nasal pharyngeal swabs (a method to collect nasal secretions from the back of the nose and throat) will be collected

Day 1 of the study:
Study medication will start as soon as the screening visit is completed (within 24 hours)
Standard Procedures include:

- You will be asked about how you are feeling
- You will be checked on how well you are breathing
- Your blood pressure, temperature, pulse, respiration and weight will be taken
- Blood (1-2 teaspoons) will be collected to check your blood counts and organ function

- Blood (1-2 teaspoons) may be collected to check on how your immune system is doing, if clinically indicated
- Urine will be collected to check your kidney function
- A chest X-ray may be needed, if clinically indicated
- Blood and/or sputum specimens may be collected if your treating physician needs to run cultures

Non-Standard Procedures Include:

- You will receive investigational drugs atovaquone by mouth twice daily and azithromycin by mouth once on this day. If you cannot take the medication by mouth, your treating physician may decide to administer via a tube through your nose, mouth, or belly. Your treating physician will discuss this with you or your legally authorized representative.
- Blood will be collected for study-related analyses which are not related to your clinical care (about 1-2 teaspoons each sample)
- Nasal pharyngeal swabs will be collected

Day 2 of the study:

Standard Procedures include:

- You will be asked about how you are feeling
- You will be checked on how well you are breathing
- Your blood pressure, temperature, pulse, respiration and weight will be taken
- An electrocardiogram may be performed to check your heart, if clinically indicated
- Blood (1-2 teaspoons) will be collected to check your blood counts and organ function
- Blood (1-2 teaspoons) may be collected to on how your immune system is doing, if clinically indicated
- Urine will be collected to check your kidney function
- A chest X-ray may be needed, if clinically indicated
- Blood and/or sputum specimens may be collected if your treating physician needs to run cultures

Non-Standard Procedures Include:

- You will receive investigational drugs atovaquone by mouth twice daily and azithromycin by mouth once on this day. If you cannot take the medication by mouth, your treating physician may decide to administer via a tube through your nose, mouth, or belly. Your treating physician will discuss this with you or your legally authorized representative.

Days 3-4 of the study

Standard Procedures include:

- You will be asked about how you are feeling
- You will be checked on how well you are breathing

- Your blood pressure, temperature, pulse, respiration and weight will be taken
- Your treating physician will perform a physical examination once during this period (between days 3 and 4)
- An electrocardiogram may be performed to check your heart, if clinically indicated
- Blood (1-2 teaspoons) will be collected to check your blood counts and organ function
- Blood (1-2 teaspoons) may be collected to on how your immune system is doing, if clinically indicated
- Urine will be collected to check your kidney function
- A chest X-ray may be needed, if clinically indicated
- Blood and/or sputum specimens may be collected if your treating physician needs to run cultures

Non-Standard Procedures Include:

- You will receive investigational drugs atovaquone by mouth twice daily and azithromycin by mouth once on this day. If you cannot take the medication by mouth, your treating physician may decide to administer via a tube through your nose, mouth, or belly. Your treating physician will discuss this with you or your legally authorized representative.
- Blood will be collected for study-related analyses which are not related to your clinical care (about 1-2 teaspoons each sample) on Day 3 only
- Nasal pharyngeal swabs will be collected on Day 3 only

Days 5-9 of the study

Standard Procedures include:

- You will be asked about how you are feeling
- You will be checked on how well you are breathing
- Your blood pressure, temperature, pulse, respiration and weight will be taken
- An electrocardiogram may be performed to check your heart, if clinically indicated
- Blood (1-2 teaspoons) will be collected to check your blood counts and organ function
- Blood (1-2 teaspoons) may be collected to on how your immune system is doing, if clinically indicated
- Urine will be collected to check your kidney function
- A chest X-ray may be needed, if clinically indicated
- Blood and/or sputum specimens may be collected if your treating physician needs to run cultures

Non-Standard Procedures Include:

- You will receive investigational drugs atovaquone by mouth twice daily and azithromycin by mouth once on this day. If you cannot take the medication by mouth, your treating physician may decide to administer via a tube through your nose, mouth, or

belly. Your treating physician will discuss this with you or your legally authorized representative.

Day 10 of the study

Standard Procedures include:

- You will be asked about how you are feeling
- You will be checked on how well you are breathing
- Your blood pressure, temperature, pulse, respiration and weight will be taken
- An electrocardiogram may be performed to check your heart, if clinically indicated
- Your treating physician will perform a physical examination
- Blood (1-2 teaspoons) will be collected to check your blood counts and organ function
- Blood (1-2 teaspoons) may be collected to on how your immune system is doing, if clinically indicated
- Urine will be collected to check your kidney function
- A chest X-ray may be needed, if clinically indicated
- Blood and/or sputum specimens may be collected if your treating physician needs to run cultures

Non-Standard Procedures Include:

- You will receive investigational drugs atovaquone by mouth twice daily and azithromycin by mouth once on this day. If you cannot take the medication by mouth, your treating physician may decide to administer via a tube through your nose, mouth, or belly. Your treating physician will discuss this with you or your legally authorized representative.
- Blood will be collected for study-related analyses which are not related to your clinical care (about 1-2 teaspoons each sample)
- Nasal pharyngeal swabs will be collected

Eleven (11) days to seventeen days (17) after you received the last dose of investigational drugs:

- You will be asked about how you are feeling and any medications you may be taking. This conversation may take place over the phone
- Blood will be collected for study-related analyses which are not related to your clinical care (about 1-2 teaspoons each sample). You will need to come to the clinic/site to provide the sample
- Nasal pharyngeal swabs will be collected. You will need to come to the clinic/site to provide the sample

Twenty-three (23) days to thirty-seven (37) days after you receive the last dose of investigational drugs, atovaquone and azithromycin, you will receive a phone call to ask how you are feeling.

You may be part of the study for up to forty-seven (47) days in addition to the screening visit.

RISKS AND DISCOMFORTS
You may have side effects while participating in this study. There may be risks to being in this study that we cannot predict or that are currently unexpected. Some of these may be life-threatening.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

If you do not understand what some of the side effects or risks mean, ask the study doctor or the study staff to explain them to you.

Atovaquone Risks
- Diarrhea
- Rash
- Headache
- Nausea
- Vomiting
- Rhinitis – inflammation of the nose (common cold)
- Fever
- Insomnia
- Liver toxicity – including elevated liver enzymes, inflammation of the liver, jaundice, liver failure leading to death.

Azithromycin Risks
- Diarrhea
- Serious allergic reactions including skin and acute reactions
- Liver toxicity – including elevated liver enzymes, inflammation of the liver, jaundice, liver failure leading to death.
- If you suffer from Myasthenia Gravis, azithromycin may aggravate your condition

During the study, we will be monitoring you closely and taking safety blood samples. You will be informed if any clinically important changes are seen and if it is required, we may need to stop the study or withdraw you from further participation.

Please be aware that many drugs can cause a serious allergic reaction in certain individuals. For example, penicillin and even aspirin can be life-threatening to some people. It is essential for this reason that you are honest regarding your past medical history, to allow the study doctor to keep you as safe as possible.

If you experience any unusual symptoms or side effects, please notify the study doctor or study staff immediately.

Serious Adverse Reactions
All possible precautions will be taken to prevent serious adverse reactions (side effects). Depending on the type of reaction, a medical specialist will be contacted to be primarily responsible for your treatment. The study doctor will provide assistance to the hospital and doctors looking after you but all hospital records are confidential and for this reason, you are being asked to give the study doctor and any emergency medical specialists contacted by the study doctor, consent to visit you and have access to your medical records.

In case of a serious adverse reaction the treating medical doctor will be allowed access to your medical records collected during the course of this clinical study in order to provide appropriate care.

Allergic Reaction Risks
There is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

If you have any of the above symptoms, let the study doctor know immediately.

You will be monitored very carefully for any signs or symptoms that you may be having an allergic reaction and appropriate care will be taken by the study doctor and study staff if a symptom is suspected.

Procedure Risks

Blood Draw/Catheter Insertion Risks
Your blood samples will be drawn either through a needle or a catheter. At the site where your blood is drawn/the catheter is inserted, you may have pain or bruising and could develop an infection and a clot can form at the site. You may feel dizzy or could faint during or after your blood has been drawn.

You will give a total of about 160 mL (approximately 1 cup and a third of blood). For comparison, one blood donation is about 500 mL (approximately 1 pint) and is considered safe to give about every 56 days. Additional blood samples may be taken, if needed, to check on your safety or for other reasons.

Electrocardiogram Risks and Telemetry
The ECGs are electrical recordings of your heart rhythm and telemetry is a continuous monitoring of your heart rhythm. To capture your heart rhythm, electrode pads will be placed on different parts of your body. If required, your hair may have to be shaven to allow appropriate contact of the electrode pads. Skin irritation may occur where the pads are placed and minimal discomfort or bruising may occur when the pads are attached and/or removed.

You may experience bruising from the blood pressure cuff and/or irritation at the site of the electrode pads applied to the skin for the ECG recordings.

Telemetry is continuous monitoring of your heart rate and rhythm. You will wear electrode pads on your chest that are attached to wires which are connected to a transmitter box. The transmitter box sends signals about your heart rate and rhythm to the remote monitoring station that is being continuously monitored by a trained staff member, usually a nurse. The telemetry pads may cause minimal discomfort and/or bruising during attachment and removal from the skin, as well as irritation where the pads are placed. This may also lead to itching and scarring. A rash may develop and resolve but lead to increased skin discoloration (increased pigmentation) which may take several weeks or months to disappear, or rarely, may be permanent. If any abnormality of your heart rate or rhythm is discovered during the continuous monitoring of your telemetry, a medical staff member will be notified as soon as possible.

Chest X-ray Risks
The amount of radiation you're exposed to during an X-ray is so small that the risk of any damage to cells in your body is very low.

Reproductive risks
It is not known if or how the study drug will affect the embryo or fetus if your female partner becomes pregnant while taking part in this study.

Men
It is not known if the study drug will affect sperm or semen. You should not father a child from before the first administration of the study medication until 3 months after final administration of study medication.

- If either you are non-fertile, i.e., surgically sterilized/had a vasectomy, or your female partner(s) is (are) of non-childbearing potential, i.e., post-menopausal (absence of menses for at least 12 months) or surgically sterilized (e.g., tubal ligation, hysterectomy in medical history), you should use a condom from before the first administration of the study medication until 3 months after final administration of study medication.
- If you are fertile and your female partner(s) is (are) of childbearing potential, you should use a condom plus spermicide agent, in addition to having your partner(s) use another acceptable method (oral or injectable hormonal contraceptives, contraceptive patch, intra uterine devices, vaginal hormonal rings, vaginal diaphragm or cervical caps) from before

the first administration of the study medication until 3 months after final administration of the study medication.

- If you are sexually abstinent, you need to be sexually abstinent from before the first administration of the study medication until 3 months after final administration of the study medication, but only if this is in line with the preferred and usual lifestyle of you. Periodic abstinence with your female partner(s) using calendar, symptothermal, post-ovulation methods, etc. is not true abstinence; subjects practicing these methods are considered sexually active.
- You should not donate sperm from the day of dosing and for 3 months after discharge from the clinical site.

Please ask the study doctor if you have any questions about the methods of birth control that must be used while participating in this research study.

If your female partner(s) becomes pregnant during the study or within 3 months after the dose of study medication, you should inform your study doctor immediately. As the risk to your female partner(s) and baby is unknown, it is desirable for your female partner(s) to agree to follow-up on the pregnancy until resolution and for the baby after it is born. Your study doctor will work with the Sponsor to organize this. The Sponsor may request you and your female partner's consent to collect confidential information about her health and that of the baby.

General Discomfort Risks
You will be asked to fast during parts of this study, which may cause you some discomfort. In addition, study requirements such as confinement to the clinical site, dietary restrictions and limitations on caffeine may also cause you some discomfort.

Unknown Risks
You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New side effects could happen to you. Tell the study doctor or study staff right away if you have any problems.

The study medication used in this study can interact with other medications, including over-the-counter medications, herbal and homeopathic preparations. Please tell the study doctor all the treatments you are currently taking.

All of the above-noted side effects represent a wide range of possibilities and it is possible that you may not experience any of them. It is also possible that you may experience other symptoms or side effects that are unforeseen or have not been observed frequently in connection with use of the study drug combination atovaquone and azithromycin. Since the study drug combination has not been given to human subjects, it is possible that unexpected side effects which are potentially life-threatening could occur.

If you should experience a skin reaction during your participation in the study, whether or not the reaction causes you discomfort or you believe the reaction is serious, a photograph of the area where the reaction appears may need to be promptly taken for evaluation and assessment purposes, as determined by the study doctor. These photographs, if taken, will remain in confidential files and will not reveal your identity. If you do not want to be photographed, you cannot participate in the study.

NEW INFORMATION
You will be told about anything new that might change your decision to be in this study. If there is new information, you may be asked to sign a new consent form.

BENEFITS
It cannot be promised that you will receive any medical benefits from being in this study.

There may be no direct medical benefit to you from participating in this study, except you may gain information about your health from the different tests that are done as part of the study. Information obtained from this study will benefit the sponsor. It might also lead to treatments that help others in the future.

COSTS
The study will provide study medications atovaquone and azithromycin free of charge during your participation in the study.

Additionally, you will not be billed for blood collection for study-related analyses and any study related procedures.

You and your insurance will be billed for any other procedures taking place during your participation. These procedures are part of the standard of care for your condition. These include:

- Blood collections and laboratories to check your organ and immune function
- Electrocardiograms
- Any radiography studies
- Any additional costs as applicable to treat your condition

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 might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

PAYMENT FOR PARTICIPATION
You will not be paid for your participation in this research.

ALTERNATIVE TREATMENT

There are no drugs or other therapies approved to prevent or treat COVID-19. Current clinical management includes infection prevention and control measures and supportive care, including supplemental oxygen and mechanical ventilation support when indicated.
Ask the study doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

CONFIDENTIALITY OF YOUR INFORMATION COLLECTED DURING THE STUDY
As required by the Federal Health Insurance Portability and Accountability Act (HIPAA), every effort will be made to safeguard the confidentiality of information that identifies you and relates to your past, present and future physical and mental health. We will do our best to make sure that the personal information obtained during the course of this research study will be kept private (such as using codes or keeping consent forms separate from data to ensure that your name and identity will not become known or linked with any information they have provided). However, we cannot guarantee total privacy. Your personal information may be given out if required by law.

Unless required by law, you will not be identified on any electronic form by name, social security number, address and telephone number or any other information that can directly identify you. The information shared with the Sponsor is protected by the use of a code, which is a number specifically assigned to you. The study doctor is in control of the code needed to connect your data to you, but the study doctor will not send the list with the code to the Sponsor. However, the study forms may contain other information about you, such as your age, sex and medical history. It is possible that this other information could be used to identify you even though your name does not appear.

The results of this study may be published by the Sponsor, including in a medical journal and shown at medical meetings. You will not be identified (by name or any other means, e.g., photo) in any of these publications.

The Food and Drug Administration (FDA) and the Western Institutional Review Board (WIRB) may inspect records related to this research, which may include your protected health information or other information about you derived or maintained as part of this study.

Information derived from this study may be used for research purposes that may include publication and teaching. However, information used for publication and teaching will not disclose your identity.

Bio-Samples

As noted previously, blood samples for research purposes will be collected at certain visits while you are participating in this study. These research samples will be used for exploratory biomarker testing. These samples will be placed in long-term storage until such time they are needed for testing.

All the samples will be processed without your name, ID number or any other information which allows your identification. They will be labeled with a code. As explained above with respect to the study data, only authorized people will have access to the list of names which links your name to the code. Only authorized members of the study doctor's staff or third parties which will assist the site with the conduct of the study (i.e. laboratories, pharmaceutical company providing the drug) will have access to the samples.

Genome Testing

Biomarker testing may involve analysis of your genome (DNA), an "instruction book" for the cells in your body. Your blood and other bodily samples may be tested for genome variations. Some of the genome variations may be inherited. Testing may include analysis of all of your DNA (whole genome sequencing) or analysis of all of your DNA that codes for proteins (whole exome sequencing). Analyses of samples from a large number of people may help researchers learn more about the drugs, the disease, possible links among diseases, genome variations and how they might affect a disease or a person's response to treatment, and new avenues for drug development and personalized therapies.

Handling of Genetic Information

Testing of your samples may provide information related to your genome ("genetic information"), including information about inherited characteristics. Your samples and genetic information will not be labeled with your name, your picture, or any other personally identifying information. HonorHealth uses many safeguards to protect your privacy.

The Genetic Information Nondiscrimination Act generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you on the basis of your genetic information. This act generally will protect you in the following ways:

- Health insurance companies and group health plans cannot request your genetic information from this research
- Health insurance companies and group health plans cannot use your genetic information when making decisions regarding your eligibility or premiums
- Employers with 15 or more employees cannot use your genetic information from this research when setting the terms of your employment

This federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

COMPENSATION FOR INJURY

We will make every effort to prevent study-related injuries and illness. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you may go to any emergency room or urgent care facility to seek medical treatment. If it is determined that the injury or illness is not related to the research, the costs of this care may be charged to you or to your health insurer. No funds are routinely available from HonorHealth to compensate you for a study-related injury or illness. This does not mean that you are giving up any of your legal rights.

The study doctor will provide you medical care if you need it, and will also treat you for any complications that may occur during your participation in the study. If you become ill or are injured as a direct result of your participation in this study, you will be provided the reasonable and necessary treatment for that injury or illness. The bills for the injury or illness not caused by study participation may be billed to your medical insurance or to your third party or governmental programs in which you participate.

The sponsor agrees to reimburse costs for documented medical expenses for injury or illness caused by administration of study drug in accordance with the protocol or any properly performed procedures required by the protocol. The Sponsor will not reimburse costs for injury caused by your failure to follow your study doctor's or study staff's instructions for the study. The Sponsor will not offer to pay costs of medical care for such an injury or items such as lost wages, expenses, compensation for pain and suffering, discomfort and disability. Please speak with your study doctor to make sure you understand your options regarding compensation for injury.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to take part or you may leave the study at any time. Your decision will not cause any penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- it is in your best interest,
- you do not consent to continue in the study after being told of changes in the research that may affect you,
- or for any other reason.

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

SOURCE OF FUNDING FOR THE STUDY
HonorHealth is funding this study. The study doctor is being paid by HonorHealth as part of their employment. The study doctor is not receiving any other payment to conduct this research study.

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 protected health information (PHI). The document you are reading, called an "Authorization," explains how your PHI will be used and disclosed (shared) for purposes of the research study and describes your rights with respect to such information.

What information will be collected by the study doctor and his research staff for this study?
The study doctor will collect your personal and medical information. This may include:
- Past and present medical records,
- Research records,
- Records about phone calls made as part of this research,
- Records about your study visits.

Who may use and give out information about you?
The study doctor and his research staff conducting the research.

Who will receive your personal and medical information collected?
Information from this study will be given to the study sponsor. "Sponsor" is the person or entity that initiates, provides oversight of activities within the study, and includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study. Medical records which identify you and the consent form signed by you will be looked at and collected for research purposes by:
- HonorHealth Research Institute, the sponsor and study site
- Translational Genomic Research Institute (TGen)

Your information <u>may</u> be given to:
- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported,
- Western Institutional Review Board (WIRB®)
- HonorHealth Human Subjects Research Protection Program (HSRPP)

The HonorHealth HSRPP and the HonorHealth Research Institute have the authority to review and monitor all records related to this research.

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

- for research purposes as described in this consent form,
- for consideration by the FDA or any governmental agencies in other countries for drug approval,
- to make sure the study was conducted as approved by the IRB.
- to be used for future research purposes

What will happen if you decide not to give permission to use and give out your private health information?
You cannot be in this research study.

Will you have access to the information collected during the study?
To maintain the integrity of this research study, you will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you may request access to your health information that HonorHealth maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at HonorHealth. If it is necessary for your care, your health information will be provided to you or your physician.

Does this authorization expire?
This authorization does not expire unless it is canceled by you in writing.

Can this authorization be withdrawn or canceled?
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. Absolute confidentiality cannot be guaranteed because of the need to give information to these parties.

QUESTIONS
Contact Dr. Michael Gordon, MD at 480-323-1350 (24 hours) for any of the following reasons:

- if you have any questions about your participation in this study,
- if at any time you feel you have had a research-related injury or a reaction to the study drug, or
- if you have questions, concerns, or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE, Suite 120
Puyallup, Washington 98374
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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.

CONSENT
I have read this consent form and understand what has been discussed. All my questions about the study and my part in it have been answered. I voluntarily 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.

By signing this consent form, I have not given up any of my legal rights.

All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.

If assent is obtained, have the person obtaining assent document assent on the consent form.

CONSENT SIGNATURES:

_____
Subject Name (printed)

_____ _____
Signature of Subject, if capable Date

_____
Name of Person Conducting Informed Consent Discussion (printed)

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Subject's Legally Authorized Representative or Relationship to Subject

Statement of person conducting consent with a Subject's Legally Authorized Representative (LAR):

I confirm that I have explained the study to the extent compatible with the LAR's understanding, and the LAR has agreed the subject may participate in the study.

_____
Name of Person Conducting Informed Consent Discussion (printed)

_____ _____
Signature of Person Conducting Informed Consent Discussion | Date

ASSENT DOCUMENTATION:

- ❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

- ❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining assent | Date

---------- Use this witness section only if applicable ----------

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

Signature of Impartial Witness | Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.