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Official Title: A Phase II Trial of High-Dose Ascorbate in Stage IV Non-Small Cell Lung Cancer

Principal Investigator: Muhammad Furqan, M.B., B.S.

Co-Principal Investigator: Bryan Allen, MD, PhD

IND Sponsor: Joseph J. Cullen, MD

Protocol Number: NCT02420314

IND Number: 105715 [CDER]

IRB of Record: University of Iowa IRB-01

Document: Informed Consent Document

Document date: 22 January 2020

INFORMED CONSENT DOCUMENT

Project Title:	A Phase II Trial of High-Dose Ascorbate in Stage IV Non-Small Cell Lung Cancer	
Principal Investigator:	Mohammad Furqan, M.B., B.S.	
Research Team Contact:	Mohammad Furqan, M.B., B.S. (319) 356-4200	Bryan G. Allen, MD, PhD (319) 356-3693

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

What is the purpose of this study?

This is a research study. We are inviting you to participate in this research study because you have been diagnosed with lung cancer and your doctor has recommended chemotherapy for treatment.

The purpose of this research study is to determine if pharmacological ascorbate (high-dose vitamin C) increases treatment effectiveness. We do not know how pharmacological ascorbate affects treatment.

Pharmacological ascorbate (high-dose vitamin C) is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

How many people will participate?

Approximately 57 people will take part in this study conducted by investigators at the University of Iowa.

How long will I be in this study?

If you agree to take part in this study, your active involvement will last for about 5 months. You will have life-long follow-up for this study.

- You will receive high-dose ascorbate chemotherapy twice a week for about 12 to 14 weeks total. Each infusion lasts about 2 ½ hours.
- We will meet with you when you meet with your medical oncologist, about once a month. This will add about 20 minutes to this doctor's visit.
- You will receive chemotherapy once every 21 days, as you are able. This infusion takes about 4 ½ to 5 hours on average. You will have chemotherapy up to 4 times for this research study.

- We will meet with you after you complete the study treatment. This visit will be at your 1 month checkup. This will add about 10 minutes to each of those doctors' visits.
- After this visit, we will review your UIHC medical record to find out how you are doing. If you no longer come to UIHC for your cancer care, we will contact your local physician or oncologist.

You will have life-long follow-up for this study. That means when you are no longer receiving the ascorbate (the study drug), we will still want to find out how you are doing. This is because the drug is investigational. We may visit you during your scheduled cancer treatment appointments or speak with your cancer doctors about how you are doing. We will review your UIHC medical chart about 4 times a year. If you no longer come to UIHC for your cancer care, we may contact you, any alternative contacts you provide us for this study, the emergency/alternate contact listed in your medical records, or your local physicians to find out how you are doing. If we do not have your current address, we may do an internet-based search to find where you are currently living and contact you by mail or phone, based on the results of that search.

What will happen during this study?

Before you begin the study treatment

You will need to have some blood tests done to find out if you can continue to be in the study. Some of these tests are part of regular cancer care and may be done even if you do not join the study treatment. If you have had some of them recently, they may not need to be repeated. This is up to your doctor.

- Blood will be taken to determine blood counts, kidney function, liver function, electrolyte levels, and levels of an enzyme in your blood called G6PD. The result of the G6PD test will be added to your medical record.
- Blood will be taken to determine the level of iron in your blood. This is done for the study but the results will be added to your medical record and shared with your doctors.
- Pregnancy test (if you are a woman of child-bearing potential). The results of this test will also be added to your medical record.
- Three baseline blood samples (one for ascorbate, and two for molecules and markers affected by cancer treatment) will be drawn. These are baseline samples that will be used if you continue on study. If you do not continue on study, they will be destroyed. These results are not entered into your medical record.
- A fingerstick glucose reading. This will not be entered into your medical record.
- A 15 gram test dose of ascorbate *via* IV infusion.

IMPORTANT. High dose ascorbate may interfere with finger-stick blood glucose readings. **If you are using a finger-stick glucometer, you must discuss this with the study doctor,** as you may not be able to participate in this study.

We will provide you a pocket card you can carry with you. You should, or a caregiver, should provide this to a healthcare professional during any treatment you receive away from UIHC.

During your study treatment

If the tests show you can proceed, you will begin chemotherapy and ascorbate acid. You will receive study treatment for approximately 12 to 14 weeks or until your disease progresses. Information about your ascorbate therapy, including the dose and your response to it, will be added to your medical record. This means other doctors can see that you are being treated with ascorbate.

You will receive the same chemotherapy you would if you were not in this study:

1. You will receive paclitaxel and carboplatin (chemotherapy treatments) once every 21 days (3 weeks). This treatment lasts about 4 ½ to 6 hours.
2. You will visit your doctor to find out how you are doing about once every three weeks (before you are due to have your chemotherapy treatment).
3. You will have blood tests standard for your cancer care. They check how your kidneys, liver, and bone marrow are functioning. You would have these tests if you were not in the study.
4. We will draw blood for iron tests during cycle 1 and 3 of your chemotherapy. This is done for the study but the results will be entered into your medical record and shared with your doctors.
5. When you have your blood tests, we will draw two extra tubes of blood for research purposes (about 2 tablespoons). This is to measure molecules or markers that might suggest how the ascorbate is affecting you. This information is not added to your medical record.
6. You will have two extra tubes of blood (about 2 tablespoons) drawn for research purposes on your chemotherapy cycle day 2. This is to measure the molecules or markers that might suggest how the ascorbate and chemotherapy are affecting you. This information is not added to your medical record.

You will receive pharmacological ascorbate (high-dose vitamin C) infusions:

1. You will get an ascorbate infusion twice a week. We will schedule these infusions for you. They will be in the Cancer Center's infusion suite.
2. Each infusion takes about 2 hours to complete and has 75 grams of ascorbate with each infusion.
3. Once every three weeks, we will draw a blood sample (about 1 tablespoon) before and after the infusion. This is to check the ascorbate levels in your blood. Occasionally, we may need to draw additional samples to check the ascorbate levels. This could be to verify a measurement or because the other blood sample couldn't be analyzed for ascorbate. This information will not be added to your medical record.
4. On the day we draw a blood sample, we will also test your blood for ascorbate using a finger-stick glucometer. These are the same type of tests diabetics use to check blood sugar. This information will not be added to your medical record.
5. If you do not feel well, or have a reaction to the ascorbate, you may need to stay longer. If this happens, you will stay until the doctor decides you are able to leave.
6. Your last ascorbate infusion is on the last day of cycle 4 of your chemotherapy.

Radiation Therapy

During this clinical trial, if you require radiation therapy (for example, to reduce pain), chemotherapy and ascorbate therapy will need to be paused. There will need to be about a 3 day break between chemotherapy or ascorbate therapy and the start of radiation therapy. There will also need to be this type of break before you restart your therapy.

After your study treatment

1. We will schedule a follow-up appointment in the Holden Comprehensive Cancer Center that is about 20 to 30 days after your final ascorbate treatment. It is very important you keep this appointment. We will draw one last blood sample for research to look at the markers and molecules that might have been affected by your study treatment.
2. Your next follow up appointments will be scheduled every 3 months for 2 years. This is normal for your cancer care. It is important that you keep these appointments so we know how you are doing. We also need to speak with you to see if there are any side effects from the ascorbate.
3. After your 2 year appointment, your active participation in the study is complete. We will still follow your progress, though. This is done by reviewing your chart to find out how you are doing. We may also visit you during one of your cancer appointments or contact you by phone. If you no longer use UIHC for your cancer care, we may contact you or your local doctor. If needed we may use hospital contact information or an internet search to keep in contact with you. If we do not have your current address, we may do an internet-based search to find where you are currently living and contact you by mail or phone, based on the results of that search.

Health-Related Quality of Life (Optional)

We are interested if the ascorbate (vitamin C) makes patients feel better during their therapy. The way to know this is to have people participating in the study complete questionnaires. This is optional – if you would prefer not to do it, you do not have to.

If you agree to participate:

- You will complete a questionnaire before each dose of chemotherapy.
- We will also ask you to complete a questionnaire before your last dose of chemotherapy (after about 12 weeks of therapy)
- The questionnaires will take about 10 to 15 minutes to complete.
- You can skip any question you don't want to answer. So we know you don't want to answer it, put a line through it (----------)

Please place your **initials** in the blank next to Yes or No for the question below:

I agree to participate in the health-related quality of life.

_____ Yes _____ No

Tissue & Blood Storage for Future Use

As part of this study, we are obtaining blood from you. If you have had surgery, or have further surgery, we would also like to get a sample of any tumor tissue. We would like to study your blood and tumor tissue in the future, after this study is over.

The tests we might want to use to study your blood and tumor tissue may not even exist at this time. Therefore, we are asking for your permission to store your blood and tumor tissue so that we can study them in the future.

These future studies may provide additional information that will be helpful in understanding lung cancer, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood and tumor tissue might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your blood and tumor tissue, but decide in the future that you would like to have it removed from future research, you should contact Dr. Muhammad Furqan at (319) 356-1616. However, if some research with your blood and tumor tissue has already been completed, the information from that research may still be used.

Please place your **initials** in the blank next to Yes or No for each of the questions below:

My blood may be stored/shared for future research.

_____ Yes _____ No

My tumor tissue may be stored/shared for future research.

_____ Yes _____ No

What are the risks of this study?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Research related risks

Intravenous Ascorbate (Vitamin C)

Serious

- Diarrhea <10%
- Nausea or vomiting <5%
- Kidney stones <5%
- Precipitation of cystine, oxalate or urate crystals in the kidney resulting in kidney damage or failure <1%
- Seizure associated with infusion (<5% - this has occurred only in patients with brain cancers)

Mild

- Dry mouth/thirst (>35%)
- Chills (thought to be related to the cool temperature of the IV solution) (>35%)
- Headache <5%
- Fatigue <5%
- Facial flushing <5%
- Sweating <5%
- Weakness <5%
- Injection site irritation may occur <2%
- Faintness or dizziness may occur with rapid IV administration <5%
- Abdominal pain <5%
- Increase in iron levels which could potentially cause liver damage
- Risk of gout, gout-like symptoms, or exacerbation of existing gout (<2%)

Medical Imaging

There is a risk that ascorbate could interact with contrast used for medical imaging (CT or PET/CT), causing an increase in liver function tests. For this reason, you should let us know if you have any medical imaging scheduled during your chemotherapy / ascorbate treatments. We will not schedule ascorbate treatments on days you are scheduled to have medical imaging.

Blood Glucose Readings

High dose ascorbate (like you are receiving for this study) has been shown to interfere with finger – stick blood glucose readings. It creates a false (fake) high value. This means after you receive the ascorbate infusion, a finger-stick glucometer would show very high levels of blood sugar, even though your blood sugar is normal. This is also true for a urine analysis. Your urine would show high levels of sugar in it because of the ascorbate. We do not know how long these false readings last.

It is important that you tell your doctor right away if another doctor has requested you monitor your blood sugar or test your urine. Also, if you see another doctor, it is important to let him or her know that a finger stick or urinalysis might have false values.

If you need to have your blood sugar checked by a finger-stick test, or a doctor has told you to start checking your blood sugar with a finger-stick test, **you must tell us immediately**. Call 319-356-1616 and ask for the hematology-oncology fellow on call. When the operator connects you, tell the doctor you are participating in Dr. Furqan's Vitamin C for Lung Cancer study.

Radiation Risk

In addition to the experimental chemotherapy with the Ascorbate drug, it is possible that you may receive radiation treatments in the course of this study. The radiation treatments are considered standard care for your condition. Even though administration of the Ascorbate drug will be paused for at least 72 hours before any radiation therapy treatment, any remaining Ascorbate in your body may intensify radiation effects on some normal tissues, and increase the risk of radiation-related side effects. Short-

term risks include skin changes such as redness, hair loss, or delayed wound healing; and long-term risks include causing a new tumor.

Risks associated with standard chemotherapy

Carboplatin

Likely

- A decrease in white blood cells, which could lead to infection
- A decrease in platelets, which could lead to bleeding
- Nausea and/or vomiting
- Diarrhea
- Fatigue
- Loss of hair
- Temporary changes in blood tests which measure kidney or liver function
- Low sodium in the blood, which could result in bloating and puffiness in the face and fingers, nausea, vomiting, muscle weakness, headache, and disorientation
- Low magnesium in the blood, which could result in increased irritability of the nervous system with spasms of the hands and feet, muscular twitching, and cramps
- Low calcium in the blood, which could result in numbness or tingling around the mouth or in the feet and hands, as well as in muscle spasms in the face, feet, and hands
- Low potassium in the blood, which could result in muscle weakness, cramping, muscle limpness, and/or irregular heartbeat

Less Likely

- Weakness, loss of strength
- Pain
- Mouth sores
- Tingling, numbness, burning pain in hands and feet, which may be persistent or permanent
- Inflammation of the lung, which could lead to cough and shortness of breath

Rare but serious

- Blurred vision
- Hearing loss
- Allergic reactions
- Irregular heartbeats
- Shortness of breath
- Hemolytic-uremic syndrome (HUS), a disorder that results in the destruction of red blood cells and platelets with decreased kidney function
- A risk of developing a second cancer unrelated to the treated lung cancer, which may occur months or years after initial treatment
- Death

Paclitaxel

Likely

- Low pulse
- Low blood pressure
- Loss of hair
- Tingling, numbness, burning pain in hands and feet
- A decrease in white blood cells, which could lead to infection
- A decrease in platelets, which could lead to bleeding
- Skin redness or rash
- Fatigue
- Nausea and/or vomiting
- Mouth sores
- Diarrhea
- Anemia, a lower than normal number of red blood cells
- Swelling of the legs, arms, or feet
- Cardiovascular changes on EKG (test that measures electrical signal of heart)

Less Likely

- Injection site reaction
- Blurred vision
- Skin or nail darkening
- Aches and pains in muscles and joints
- Fever

Rare but serious

- Temporary changes in blood tests measuring liver function
- Abnormal heart rhythms, which could be life threatening
- Severe allergic reactions
- Temporary "bright spots" in vision
- Severe rash called "Stevens- Johnson Syndrome" that can cause fever and severe eruptions of blisters which can occur on the skin of the trunk of the body, mouth, eyes, and genitals
- Death

Lowered Blood Counts

This study has a very likely risk of reducing your blood cell counts. This means:

- Lowered white blood cell count: this may lead to an infection.
- Lowered red blood cell count: this may cause anemia, tiredness, or shortness of breath. If your red blood cell count gets too low, you may need to receive blood transfusions.
- Lowered platelet count: may lead to bruising or bleeding. The bleeding could be serious. If your platelet count gets too low, you may need to receive platelet transfusions.

Should any of these occur, they can be treated with blood products (transfusions), antibiotics, and a reduction in the amount of chemotherapy given to you. Until your immune system recovered from treatment, any blood products you would receive would be irradiated.

If you were to have a low white cell count and get an infection, this could be a life threatening infection. For this reason, if you develop a temperature over 100 degrees, call (319) 356-1616 immediately and ask to speak to the Hematology/Oncology Fellow on call. If it is after 5 PM or on a weekend, call 319-356-1616 and ask for the Hematology/Oncology Fellow on call. Tell the Fellow you are a participant in Dr. Furqan's Vitamin C study for lung cancer.

Financial Risk

Not all insurance companies allow participation in clinical trials. Your insurance company may change your co-payments or deny payment if you participate in a clinical trial. To reduce this risk, we will contact your insurance company to determine if they cover clinical trials – but this is not a guarantee of payment. You may also have additional healthcare costs if you have a side effect from the ascorbate.

Confidentiality and Clinical Trials

By participating in a clinical trial, there is the risk of loss of confidentiality of your medical information. We will protect your confidentiality as described in the Confidentiality section of this document.

Women Capable of Becoming Pregnant

If you are a woman who is capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You cannot participate in this study if you are pregnant. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your fetus, or risks to your fetus that we did not anticipate, associated with being in the study. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. If you believe or know you have become pregnant while participating in this research study, please contact Dr. Furqan at 319-356-1616 as soon as possible.

If you believe you are experiencing a research-related injury, please contact:

> **(319) 356-1616** (24 hour telephone number)
> Ask the operator for the Hematology/Oncology fellow on call. They will connect you.
> When you are connected with the resident, tell them you are a participant in
> Dr. Furqan's Vitamin C study for lung cancer.

What are the benefits of this study?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of knowledge gained toward finding a better way to treat lung cancer.

What other treatment options are there?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive the standard treatment for your tumor (chemotherapy) or opt to be in a different clinical trial.

Will it cost me anything to be in this study?

You will have additional costs for being in this research study.

You will not be charged for:

- The study drug (ascorbate). This is provided to you by the study.
- The glucose-6 phosphatase dehydrogenase (G6PD) test. The study will pay for this.
- The iron tests done at before your chemotherapy and cycles 1 and 3. The study will pay for these.
- The blood tests to determine the ascorbate levels in your blood. These are not clinical tests and are provided by the study.

You (and your insurance company) will be charged for:

- Infusion of the study drug (ascorbate). You should check with your insurance carrier about these costs before agreeing to participate.
- The chemotherapy (carboplatin and paclitaxel) and its infusion. This is standard for your cancer.
- Any imaging, including CT, MRI, or CT/PET imaging. This is standard for your cancer.
- Your doctors' visits and any ordered blood tests. You would have those normally for your cancer care.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

Will I be paid for participating?

You will not be paid for being in this research study.

Who is funding this study?

The National Cancer Institute (NCI) is funding this research study. This means that the University of Iowa is receiving payments from the NCI to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NCI for conducting this study.

What if I am injured as a result of this study?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

What about confidentiality?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- the U.S. Food and Drug Administration (FDA)
- The National Institutes of Health (NIH)
- The National Cancer Institute (NCI)
- The Holden Comprehensive Cancer Center
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will keep study documents and binders in locked offices. Electronic information will be stored on password protected computers. Where feasible, we will use a research ID to minimize using your name. All printed documents are stored in a locked office at the hospital. Any blood samples that we take for research testing are dated and named using your Research ID. They are also stored at the University in a locked room. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document in your medical record chart that you are participating in this study. The information included in the chart will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

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.

Will my health information be used during this study?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your healthcare provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your treatment. Once your healthcare provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, the U.S. Food and Drug Administration, the National Institutes of Health, and the Data and Safety Monitoring Board of the Holden Comprehensive Cancer Center.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your healthcare provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to:

Muhammad Furqan, M.B., B.S.
Department of Internal Medicine
C21-K General Hospital
University of Iowa Hospitals & Clinics
Iowa City IA 52242

However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

Is being in this study voluntary?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to discuss your cancer treatment plans with your doctors so that you continue to receive clinical treatment for your cancer. We will also:

- need to take blood samples to make sure your kidneys, liver, and bone marrow are functioning
- meet with you to discuss the side effects, if any, you had from ascorbate

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers or study sponsor might decide to end your participation in this research study earlier than planned. This might happen because you have a bad reaction to the study drug or because in our judgment it would not be safe for you to continue.

What if I have questions?

We encourage you to ask questions. If you have any questions about the research study itself, please contact:

Muhammad Furqan, M.B., B.S.
Phone number: 319-356-1527

If you believe you are developing any side effects, or are having symptoms that you are concerned about, please contact:

Muhammad Furqan, M.B., B.S.
(319) 356-4200 *telephone* (Monday through Friday, 8 a.m. – 5 p.m.)
tell the nurse that you are a participant in Dr. Furqan's Vitamin C study for lung cancer.

If you believe you are experiencing a research-related injury, please contact:

Muhammad Furqan, M.B., B.S.
(319) 356-4200 *telephone* (Monday through Friday, 8 a.m. – 5 p.m.)

or

(319) 356-1616 (24 hour telephone number)
Ask the operator for the Hematology/Oncology fellow on call. They will connect you.
When you are connected with the fellow, tell them you are a participant in
Dr. Furqan's Vitamin C study for lung cancer.

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If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)