PHASE II PILOT STUDY OF SUBSEQUENT LINE GEMCITABINE AND NIVOLUMAB FOR ADVANCED SMALL CELL LUNG CANCER

Informed Consent Form to Participate in Research
Thomas Lycan, DO, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to find additional combinations of chemotherapy that may be effective for patients who have incurable small cell lung cancer that has gotten worse after being treated with platinum chemotherapy (including either cisplatin or carboplatin). You are invited to be in this study because you have incurable small cell lung cancer. Your participation in this research will involve 7 visits (possibly more if your doctor feels it is needed) and last about 20 weeks unless your disease progresses. You will then be contacted every 8 weeks for the rest of your life to determine your progress.

Participation in this study will involve you receiving a new drug combination to treat your cancer. The treatment will include nivolumab and gemcitabine together. You will receive this combination for 8 weeks. During this time and after, you will be assessed for progression and provide blood samples for research. All research studies involve some risks. A risk to this study that you should be aware of is fatigue, shortness of breath, diarrhea, or autoimmune problems. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include taking nivolumab alone, other chemotherapy, or no treatment. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Thomas Lycan.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board or the Research Subject Advocate at Wake Forest

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have incurable lung cancer. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent

document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to find additional combinations of chemotherapy that may be effective for patients who have small cell lung cancer that has gotten worse after being treated with platinum chemotherapy (including either cisplatin or carboplatin).

Nivolumab is an immune checkpoint inhibitor (immunotherapy) that has been approved by the Food and Drug Administration (FDA) for other types of lung cancer including small cell lung cancer but not in combination with gemcitabine.

Gemcitabine is a lung cancer chemotherapy drug that also has been approved by the Food and Drug Administration (FDA) for other types of lung cancer but not for small cell lung cancer and not in combination with nivolumab.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be approximately 29 people at one research site that will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

You will have been identified in the clinic as a potential candidate for this study. Once you sign this informed consent you will fulfill the needed pre-study requirements, some of which may already have been collected through your standard care.

Pre-Study Requirements

Before the study begins we will ensure you are eligible for the study by collecting your medical information. This information will include demographics, medical history, current medication use, vital signs, your height and weight, and your performance status (a measure of how your cancer is affecting you). You will also give blood so that we can examine the make-up of your blood to make sure your organs are functioning and/or to make sure your blood readings are within certain limits. If you are a woman of childbearing potential and you have not taken a recent pregnancy test, you will be asked to have a pregnancy test. We will also take tumor measurements from pictures of of your tumor(s). Finally, we will ask for an extra blood sample of about 8 teaspoons that will be used for research.

Treatment Phase

You will be started on treatment with both nivolumab and gemcitabine. You will receive these drugs in cycles. A cycle of drug administration is a period of time when you take the drug and then let your body recover. You will give 1-5 teaspoons of blood at the beginning of each cycle and this is a part of your standard care so that we can examine the make-up of your blood to make sure your organs are functioning and/or to make sure your blood readings are within certain limits. This means you would give this blood even if you were not on the study. The cycles of drug are described below. In this study the cycles will last 2 weeks each and you will be treated for 4 cycles for a total of 8 weeks.

You will have 4 cycles of both nivolumab and gemcitabine and all 4 cycles will be like the process described below for cycle 1: Cycle 1 Day 1.

- You will give blood for routine clinical testing
- You will receive nivolumab and gemcitabine through a vein

Days 2-14

- You will not receive any drug

You will repeat this for the next 3 cycles

Your physician may recommend you continue chemotherapy after the 4 cycles have been completed depending upon how your disease is responding.

After Chemotherapy Phase

Once you have taken all 4 cycles of chemotherapy, your tumor will be measured by either CT or MRI imaging. You will also have a physical exam and your vital signs will be recorded. This will all be a part of your standard care. You will also give 8 teaspoons of blood for research purposes.

Follow-up Phase

The follow-up phase will take place after chemotherapy. We will follow you for 30 days after you take your last study drug. At or around 6-10 weeks after your last study drug administration you will come back in for a physical exam, vital signs, tumor imaging, and you will give blood for clinical blood work. This is all part of your standard care. You will also give 8 teaspoons of blood for research purposes.

IF YOU TAKE PART IN THIS STUDY, YOU WILL HAVE THE FOLLOWING TESTS AND PROCEDURES:

Blood Draws

You will have approximately 8 teaspoons of blood withdrawn from a vein 9 times; before study treatment starts, at the beginning of each treatment cycle, at the end of treatment, and then in a follow-up period sometime after treatment. These 6 draws will be a part of your standard care. At 3 of these blood draws (before the study treatment starts, at the end of treatment and in follow-up after treatment) you will have 8 extra teaspoons of blood collected to test for research purposes. The total amount of blood withdrawn during the study will be approximately 18-54 teaspoons from 9 draws over the length of the study.

Imaging of your Tumor(s)

You will have your tumors measured. To do this we will need to take pictures of your tumors by one of two methods. Your doctor will decide which type of imaging is best in your situation. You may have Magnetic Resonance Imaging (MRI) or Computed Tomography (CT). You will have this done at the beginning of the study and after treatment is completed (8 weeks after treatment starts). This imaging is a part of your standard care and would be done even if you were not in the study.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study. The types of tests that may be made available are routine blood tests, your response to therapy, type of therapy, and other information related to your care.
Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

Your information or biospecimen that will be collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research.

Storage of Biological Tissue

If you agree to participate in this study, we will draw blood up to 8 teaspoons of blood 3 times to use this research project and the remainder will be stored for future research. This research includes analysis of your blood samples for immune cell function. This sample will be kept and may be used in future research to learn more about other diseases. Your sample will be obtained and then initially stored in the Comprehensive Cancer Center at Wake Forest University Baptist Medical Center. The sample will then be transferred for storage and analysis by researchers approved by Dr. Thomas Lycan. An Institutional Review Board (IRB) must also approve any future research study using your blood sample. In order to participate in this study, you must be willing to provide this sample for future research.

Your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

Your blood sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

It is unknown as to what the blood will be used for in future research but may include tests that look at your and your tumor's DNA make-up, or the components (cell and molecules) that are in your blood. Your blood may be used for research not related to your disease. Your blood may be used in some animal research.

How Long Will I Be in the Study?

You will be in the study for about 20 weeks unless your disease progresses. We will then follow your progress by reviewing your chart, every 8 weeks for the rest of your life.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. This may include progression of cancer and/or late complications of cancer treatment which can go unrecognized without monitoring.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the drugs we are studying include:

Risks of Nivolumab

In general, nivolumab has a risk (>10%) of developing autoimmune complication(s), such as inflammation of the thyroid (hypothyroidism or hyperthyroidism), colon (colitis), lungs (pneumonitis), liver (hepatitis), or pituitary gland (hypophysitis), which can lead to the symptoms noted below. Autoimmune complications can potentially be life-threatening or permanent. In some cases they may be reversible with urgent administration of steroids and other immunosuppressant(s).

More common (>10% of patients):

- back painchest tightness
- chills
- constipation
- cough
- depressed mood
- diarrhea
- dry skin and hair
- feeling cold
- fever
- flushing
- hair loss
- headache
- hoarseness or husky voice
- itching
- joint or muscle pain
- muscle cramps and stiffness
- nausea and vomiting
- red, irritated eyes
- slowed heartbeat
- skin rash
- sore throat
- sores, ulcers, or white spots in the mouth or on the lips
- trouble breathing
- unusual tiredness or weakness

- weight gain
- stuffy or runny nose **Less common (<10% of patients):**
- chest pain dark urine general feeling of discomfort or illness light-colored stools nervousness pain
  sensitivity to heat stomach cramps
  sweating swelling of the face, feet, or
  lower legs tenderness
- thickening of bronchial secretions
- trouble sleeping
- upper right abdominal or stomach pain
- watery or bloody diarrhea
- weight loss
- yellow eyes and skin

Rare (<1% of patients)

- bloating
- bloody or cloudy urine
- blurred vision or other change in vision
- darkening of the skin
- dizziness
- drowsiness
- eye pain
- fainting
- fast heartbeat
- indigestion
- loss of appetite
- mental depression
- pains in the stomach, side, or abdomen, possibly radiating to the back
- redness of the eye
- sensitivity of the eye to lightskin blistering, peeling, or looseningtearing

Risks for Gemcitabine

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Major Side Effects
You should check with your doctor immediately if any of these side effects occur when taking gemcitabine:

More common (>10% of patients):
- Bleeding gums
- blood in urine or stools
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- chest pain
- cloudy urine
- coughing up blood cough or hoarseness diarrhea difficult or labored breathing difficulty in moving difficulty in swallowing dizziness fever or chills general feeling of discomfort or illness headache
  increased menstrual flow or vaginal bleeding
- joint pain
- lack or loss of strength
- loss of appetite
- lower back or side pain
- muscle aching or cramping
- muscle pains or stiffness
- nausea
- nosebleeds
- painful or difficult urination
- pale skin paralysis
- pinpoint red spots on skin
- prolonged bleeding from cuts
- red or black, tarry stools
- red or dark brown urine
- runny nose
- shivering
- shortness of breath

- sores, ulcers, or white spots on lips or in mouth
- sore throat
- sweating
- swelling of hands, ankles, feet, or lower legs
- swollen glands
- swollen joints
- tightness in chest
- troubled breathing with exertion
- trouble sleeping
- unusual bleeding or bruising
- unusual tiredness or weakness
- vomiting
- weight loss
- wheezing

Less common (<10% of patients):

Blurred vision

- chest discomfort fainting fast, slow, or irregular heartbeat headache (sudden and severe) inability to speak nervousness

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noisy breathing pain or discomfort in arms,
jaw, back or neck pounding in the ears
seizures
slurred speech

- temporary blindness
- weakness in arm and/or leg on one side of the body (sudden and severe) **Rare (<1% of patients)** Confusion
- lightheadedness
- rapid, shallow breathing

Incidence not determined (these have been observed but it is unclear as to how common they are)

- Hives
- itching
- puffiness or swelling of the eyelids or around the eyes, face, lips or tongue skin rash

Some of the side effects that can occur with gemcitabine may not need medical attention. As your body adjusts to the medicine during treatment these side effects may go away. Your health care professional may also be able to tell you about ways to reduce or prevent some of these side effects. If any of the following side effects continue, are bothersome or if you have any questions about them, check with your health care professional:

More common:

- Difficulty having a bowel movement (stool)
- hair loss
- pain
- sleepiness or unusual drowsiness
- swelling or inflammation of the mouth
- thinning of hair **Less common:**
- Bleeding, blistering, burning, coldness, discoloration of skin, feeling of pressure, hives, infection, inflammation, itching, lumps, numbness, pain, rash, redness, scarring, soreness, stinging, swelling, tenderness, tingling, ulceration, or warmth at site

Risks of blood draws.

You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

Risks of CT and MRI

The MRI and CT scans are a part of your standard care and will be explained by your physician.

Risks of Providing Confidential or Private Information

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. Birth control should be continued for at least one month after completion of study date. If further cancer treatments are planned then birth control should be continued as directed by the treating physician. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. Because some methods of birth control are not 100% reliable, a pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential.

Contraceptive Measures for Males

Your participation in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. Such harm may be currently unforeseeable. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study and for 12 months afterwards. Medically acceptable contraceptives include: (1) surgical sterilization (such as a vasectomy), or (2) a condom used with a spermicide. Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should also promptly notify her doctor.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future.

Based on experience with clinical research studies in humans, researchers believe that the addition of low-dose chemotherapy may be able to generate a response to nivolumab in patients who have not already responded. Such a response may be able to prolong the amount of time until your cancer progresses. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have the option to continue with the usual care given to patients who have advanced small cell lung cancer. There are currently no other research studies available at this site for your disease type.

The usual care of these patients often includes several options:
1) Treatment with an immune checkpoint inhibitor (such as nivolumab). The benefit is that there may be a response with immunotherapy alone, but the risk is that the treatment will be ineffective and the disease continues to progress or that the treatment will have side effects. 2) Treatment with chemotherapy. The benefit is that there may be a response with chemotherapy alone, but the risk is that the treatment will be ineffective and the disease continues to progress or that the treatment will have side effects.
3) Stopping treatment. The benefit is that there will not be treatment toxicity without any treatment, the risk is that the cancer will continue to progress without treatment.

WHAT ARE THE COSTS?

Taking part in this study may lead to added costs to you or your insurance company. We will give you an estimate of what the added cost may be based on your particular situation and insurance coverage.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and/or effectiveness of either gemcitabine when used with nivolumab; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. However, parking will be paid for any study related visits.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest Baptist Comprehensive Cancer Center. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and

the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.
You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Thomas Lycan, DO.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** demographic information, laboratory test results, medical history, your response to treatments and medications you are or have taken.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and will be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws. If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Thomas Lycan, DO that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Thomas Lycan, DO
Medical Center Blvd
Winston-Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical

Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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 Web site at any time. Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because your condition gets worse, the principal investigator determines this study is not in your best medical interest, or the study closes.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB or the Research Subject Advocate.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the

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Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

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