Official Title: Phase I trial study of Gemcitabine and Docetaxel with Radiation in Adult Patients with high grade and greater than 5cm Soft Tissue Sarcoma of the Extremities

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Phase I trial study of Gemcitabine and Docetaxel with Radiation in Adult Patients with high grade and greater than 5 cm Soft Tissue Sarcoma of the Extremities

Informed Consent Form to Participate in Research
Dr. Shailaja KS Raj, M.D., Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to see if sarcoma recurrence can be prevented or prolonged by using chemotherapy together with radiation prior to surgery in sarcoma. You are invited to be in this study because you have high grade soft tissue sarcoma of your upper or lower limb that is aggressive and over 5 cm in size. This study is considered an early dose finding study or Phase I study. We are doing this research to identify the safest dose of chemotherapy and radiation for treatment of soft tissue sarcoma of the arms or legs. Your participation in this research will involve up to 12 weekly visits followed by every 3 month visits after surgery for 2 years.

Participation in this study will involve receiving chemotherapy with radiation before surgery for management of sarcoma. All research studies involve some risks. A risk to this study that you should be aware of is your blood counts may decrease that may need to hold or adjust doses of chemotherapy. It is important to note that the risk of side effects increases with higher doses of chemotherapy and increases with the combination of chemotherapy and radiation. You will not be reimbursed for 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 standard of care chemotherapy and or radiation done separately before surgery or just surgery upfront followed by radiation and or chemotherapy done separately. 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 Dr. Shailaja Raj MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is [redacted].

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

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 a high-risk soft tissue sarcoma. We are planning a regimen combining chemotherapy including gemcitabine, docetaxel, and radiation. 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 out what effects (good and bad) therapy with gemcitabine, docetaxel, and radiation has on your immune system. This study is considered an early dose finding study or Phase I study. We are doing this research to identify the safest dose of chemotherapy and radiation for treatment of soft tissue sarcoma of the arms or legs. It is important to note that the risk of side effects increases with higher doses of chemotherapy. The risk of side effects also increases with the combination of chemotherapy and radiation.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There may be 24-48 people taking part at this research site.

WHAT IS INVOLVED IN THE STUDY?

You will be identified in the clinic as a potential participant for this early dose finding study. It will be determined if you are fully eligible for the study. If so, you will be registered to participate in the study. The risk of side effects increases with higher doses of chemotherapy and the combination of chemotherapy and radiation.

Pre-Treatment

You will be receiving chemotherapy with gemcitabine, docetaxel, and radiation therapy before you have your surgery to remove your sarcoma. When chemotherapy is given this way (prior to surgery), it is called “neoadjuvant” chemotherapy. Before treatment, you will give blood (about 2 tubes of 10 mLs each) so we can better understand some aspects of your immune system before you have chemotherapy. This blood draw will be for research purposes.

Treatment Phase

You will have standard chemotherapy with radiation for 6 weeks. Standard means that you would have the radiation treatment as part of your normal cancer care even without being part of this research study. The specific type of radiation treatment given to you will be determined by one of our radiation oncologists, but is typically given once a day, Monday through Friday, for 6 weeks.

In this research study, a “cycle” is defined as when you receive chemotherapy with gemcitabine and docetaxel once a week plus the standard radiation treatment Monday through Friday, then let your body rest over the weekend. Hence, each cycle will be 1 week (7 days) long. You will have

up to 6 cycles of chemotherapy one day each week plus radiation therapy 5 days a week for up to 6 weeks. This combination of treatments is for research purposes.

You will give 4 more teaspoons of blood for research purposes at the start and end of treatment and 1 teaspoon of blood every week. This will happen even if you have only 1 cycle of chemotherapy. If you have to stop chemotherapy before finishing 1 cycle of chemotherapy, you will not have to give blood and will be removed from the study.

Chemotherapy with Radiation
The combination of chemotherapy with radiation does not normally happen in sarcoma and this is for research purposes. This combination of treatment will last in total up to 6 weeks. However, the combination of radiation with low doses of chemotherapy is standard of care in lung cancer and some other cancers.

Surgery
You are having surgery as a part of your normal care, called limb-sparing surgery. Limb-sparing surgery is a type of treatment for soft tissue sarcoma in the arms or legs (limbs) that avoids removal of the limb. Your doctor will explain the risks and procedures. Once the tumor is removed, we will take a portion of it for research purposes.

If you take part in this study, you will have the following tests and procedures:

Blood drawing
In this study you will give blood as a part of your standard care and as a part of research. You will have blood draws at every week for the first 3 weeks of the treatment. Then you will have blood drawn once every 3 weeks after that. These are considered a part of your standard care and would happen even if you were not in the study. Before you start chemotherapy and after you finish all of your chemotherapy, you will give about 4 teaspoons, each time (about 8 teaspoons total) for research purposes to examine your immune system. This is how we test the immune changes that the chemotherapy and radiation does to your body.

You will also give tumor tissue for research purposes after it has been removed. This is considered excess tissue and will have no impact on your surgery or care.

Identifiers (your name, address, date of birth, etc.) will be removed from the private information or bio specimens that are collected as part of this research. When the identifying information is removed, your private information or biospecimen may be used for future research studies or given to other research investigators without getting additional informed consent from you. In the future, research on your specimen may involve whole genome sequencing.

Storage of Biological Tissue:

Your blood and tissue samples 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 samples.

Your blood and tissue samples will be stored de-identified, which means that no identifying information will be stored with them. Researchers will not know the name, date of birth, medical record number, social security number, etc., of the person who donated the samples.

The research that may be performed with your blood and tissue samples is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your blood and tissue will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood and tissue samples will not affect your care.

Your blood and tissue samples 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.

How Long Will I Be in the Study?

You will be in the study for about 3 years.

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. If you have side effects that are deemed to be above and beyond the expected, you will be withdrawn from the study for your safety and treated appropriately. Otherwise, you may withdraw from the study at any time. You may receive standard of care treatments per the recommendations of your physicians.

What Are the Risks of the Study?

Being in this phase I dose finding study (i.e., it is designed to test the highest tolerable dose of chemotherapy) involves some risk to you. You should discuss the risk of being in this study with the study staff. It is important to note that the risk of side effects increases with higher doses of chemotherapy and the combination of chemotherapy with radiation. Risks and side effects related to the drugs and procedures that are in this study and include:

Possible Side Effects of Gemcitabine
(Table Version Date: January 18, 2023)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, more than 20 and up to 100 may have:
• Swelling of arms, legs, and body • Shortness of breath • Infection, including in the blood, especially when white blood cell count is low • Bruising, bleeding • Anemia which may cause tiredness, or may require a blood transfusion • Blood in urine

COMMON, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, more than 20 and up to 100 may have:
• Sores in mouth which may cause difficulty swallowing • Nausea, vomiting, diarrhea, constipation • Flu-like symptoms of muscle pain, fever, headache, chills and fatigue • Burning, numbness, tingling or "pins and needles" feelings • Rash, itching • Hair loss

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, from 4 to 20 may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Damage to the lungs and/or fluid around the lungs, which may cause shortness of breath, cough • Weight loss, loss of appetite • Drowsiness

RARE, AND SERIOUS In 100 people receiving Gemcitabine, 3 or fewer may have:
• Heart failure or heart attack which may cause chest pain, shortness of breath, swelling of ankles, and tiredness • Brain damage, posterior reversible encephalopathy syndrome (PRES), which may cause headache, seizure, blindness • Stroke which may cause paralysis, weakness, headache • Liver damage which may cause yellowing of eyes and skin, swelling • Capillary Leak syndrome which may cause fluid in the organs, low blood pressure, shortness of breath, swelling of ankles • Hemolytic uremic syndrome (HUS) which may cause anemia, kidney problems, tiredness, bruising, swelling, or may require dialysis

Possible Side Effects of Docetaxel
(Table Version Date: April 29, 2021)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, more than 20 and up to 100 may have:
• Swelling of the body • Infection, especially when white blood cell count is low • Anemia which may require blood transfusions • Vomiting, diarrhea, nausea • Sores in mouth which may cause difficulty swallowing • Tiredness • Fever • Pain in muscles • Watering, itchy eyes • Hair loss • Change in nails • Rash, itching

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Docetaxel, from 4 to 20 may have:
• Abnormal heart rate • Chest pain • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Bruising, bleeding • Liver damage, which may cause yellowing of eyes and skin, swelling • Constipation, bloating, weight loss • Numbness, pain, and/or tingling of the arms and legs, fingers, and/or toes • Change in taste

RARE, AND SERIOUS In 100 people receiving Docetaxel, 3 or fewer may have:
• Damage of the bone marrow, caused by chemotherapy, which may lead to cancer of bone marrow (leukemia) • Stevens-Johnson syndrome which may cause severe skin rash with blisters and peeling which can involve mouth and other parts of the body

You should be aware that Docetaxel may cause you to become intoxicated from the alcohol it contains. Avoid driving, operating machinery, or performing other activities that are dangerous within one to two hours after the infusion of Docetaxel. In addition, some medications, such as pain relievers and sleep aids, may interact with the alcohol in the Docetaxel infusion and worsen the intoxicating effects.

Possible Side Effects of Radiation Therapy

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 20 to 100 may have:
• Reddening, tanning, or peeling of the skin • Mild pain • Hair loss • Tiredness • Diarrhea, nausea • Anemia, which may require transfusion • Infection, especially when white blood cell count is low

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 4 to 20 may have:
• Thickening and numbness of the skin • Sores or ulcers on the skin or near the cancer location • Permanent hair loss • Bleeding from the skin • Sores in mouth which may cause difficulty swallowing • Severe infections caused by progression of local skin infections or by lowering of blood counts

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Damage to internal organs • Abnormal opening in internal organs which may cause pain and bleeding

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 Surgical Resection
You may experience heart attack, stroke, blood clot in a deep vein, urinary tract infection, acute kidney failure, blockage in a lung artery, unplanned reinsertion of a tube to help with breathing, pneumonia, unplanned hospital readmission, or unplanned return to the operating room. Death may occur on rare occasions.

Risks of Providing Private or Confidential Information
In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information.

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.

Risks of an Unpredictable Nature
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 and other risks.

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), Depo-Provera, 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. 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 ***6*** 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 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 that the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: a reduction in the size of your tumor prior to your surgery, better surgical outcomes, and/or increased prevention of the tumor spreading to other parts of your body.

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 these options:

- You could be treated with Adriamycin based chemotherapy (without dose finding) or radiation separately and not together before surgery even if you do not take part in the study.
- You could be treated with surgery before chemotherapy or radiation even if you do not take part in this study.
- You could be treated with chemotherapy (without dose finding) and radiation together, also referred to as chemoradiation, before surgery even if you do not take part in this study.

WHAT ARE THE COSTS?

Taking part in this study may lead to some added cost to you. Although the aim of the research is to study the effects of chemotherapy and radiation therapies in combination, both therapies are considered part of regular medical care for your sarcoma and will be billed to you or your health insurance provider. Talk to your health insurer and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Procedures related directly to this study, such as data collection from your medical record or the research blood draws, surgical tissue collection, and their storage will be paid for by the study and not billed to you or your insurance provider.

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. Information that identifies you will be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

Your health 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 effectiveness of the combination of gemcitabine and docetaxel with radiation; 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.
The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

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 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, at [redacted].

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 Dr. Shailaja Raj MD at [redacted] after hours or the on-call Hematology/Oncology fellow at Wake Forest Baptist Health hospital immediately.

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**:** your history with relevant past medical, family and Social history along with scans , pathology reports and doctors notes describing any current or previous medical condition that may be necessary as part of the current study.

Protected Health Information will be collected from you during this study will be placed in your medical record, and may 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 at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.
You can tell Dr Raj 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:

Dr Shailaja Raj MD


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 because 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 consequences. The investigators also have the right to stop your participation in the study at any time. This could be because there may be new information published or reported at major meetings, or undue side effects experienced by any other study participant that relates to the safety of participants encourage you to talk to the investigators or study staff first to learn about any potential health or safety.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study. Clinically relevant research results will also be disclosed to you.

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, Dr. Raj at [redacted].

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 IRB at [redacted] or the Research Subject Advocate at [redacted].

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 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