Wake Forest®
School of Medicine

Department/Section of *Radiation Oncology*

A Phase II Study of Intrabucally Administered Electromagnetic Fields (TheraBionic) and Regorafenib as Second-line Therapy For Patients with Advanced Hepatocellular Carcinoma

Informed Consent Form to Participate in Research
Ravi Paluri, MD Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to find out what effects (good and bad) regorafenib - a drug used for the treatment of liver cancer like yours - and the TheraBionic device have on you and your condition. You are invited to be in this study because you have been diagnosed with liver cancer and have received treatment with at least one other standard drug (examples include Sorafenib, Lenvatinib, or Atezolizumab + Bevacizumab) or experimental treatment. Regorafenib is a standard of care medicine for your cancer. Regorafenib (Stivarga®) is the first drug to be approved for the treatment of hepatocellular carcinoma (HCC) in patients whose cancer got worse during or after sorafenib therapy. Regorafenib interferes with the growth of cancer cells. You could be prescribed regorafenib whether or not you take part in this study. The TheraBionic device is a small portable device that is believed to interfere with the growth of cancer cells by directing radio waves at the tumor. Using the TheraBionic device combined with regorafenib is experimental. Your participation in this research will involve multiple visits and last until your cancer progresses (gets worse) or you withdraw from the study.

If you participate in this study you will receive the drug regorafenib and use a device called the TheraBionic device. All research studies involve some risks. A risk to this study that you should be aware of is side effects from regorafenib. Regorafenib can cause serious liver damage. The most common risks of regorafenib are:

•pain, including stomach-area (abdomen) •tiredness, weakness, fatigue •frequent or loose bowel movements (diarrhea) •decreased appetite •infection	•voice changes or hoarseness •increase in certain liver function test •fever •swelling, pain and redness of the lining in your mouth, throat, stomach and bowel (mucositis) •weight loss

There are some risks to using the TheraBionic device. You may have fatigue, irritation of your mouth, or vivid dreams.

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 receiving regorafenib alone, which is FDA approved for liver cancer, receiving similar drugs without being in a research study, or participating in a different research study. By enrolling in this study, you are potentially foregoing the benefit from other approved drugs including cabozantinib, ramucirumab, nivolumab (with or without ipilimumab), and pembrolizumab. 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. Ravi Paluri. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is 336-713-3600.

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 liver cancer and previously have been treated with at least one other drug therapy. 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) regorafenib combined with the TheraBionic device has on you and your condition.

Regorafenib has been approved by the FDA as a second line treatment for liver cancer. The TheraBionic device (also called AM RF EMF) has not been approved by the US Food and Drug Administration (FDA).

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

25 people at Wake Forest Baptist Medical Center will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

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

Regorafenib- If you take part in this study you will be prescribed regorafenib. You could be prescribed regorafenib whether or not you take part in this study. You will receive regorafenib to treat your cancer. It may normally be part of your standard care. However, in this study, this drug will be used with the AM RF EMF treatments.

TheraBionic- This treatment consists of delivering low levels of radio waves into your body with a spoon-shaped antenna placed in your mouth. You will not be able to feel the radio waves. The frequency of these waves is about the same as a cellphone held very close to your ear. You will do this 3 times a day, for an hour each time unless your cancer progresses, you have side effects that prevent you from continuing treatment, or if you decide not to be in the study anymore. Researchers believe that the radio waves will interfere with the growth of the cancer.

Pre-Study
If you decide to take part in this study, you will sign this informed consent document and attend a clinic visit where you will provide information to determine if you are eligible for this trial. This visit will take place within 2 weeks after signing this document at your regularly scheduled clinic visit.

The type of assessments and information gathered during this time include: your medical history, demographic information, the medications you are currently taking and past treatments for your cancer. You will also receive a physical exam, including an oral exam, and have small amounts of blood taken to make sure that your organs are healthy enough for the study. If you are a woman, you will take a pregnancy test because it is not safe to take regorafenib if you are pregnant. You will undergo a CT scan and MRI, unless you recently received these for your medical care.

You will also be asked to donate about 2 teaspoons of blood for future research studies. This research blood draw will also be done at future clinic visits (about 2 teaspoons each time) and drawn at the same time as your routine care lab blood samples so that you have only one needle stick.

Treatment
If you have met all the pre-study requirements, you will be enrolled in the study. In this study, you will take "standard of care" regorafenib for your cancer. Standard of care means you would receive this even if you were not in the study. Also, you will use a TheraBionic device 3 times a day. Your first session will take place in the Comprehensive Cancer Center. After that, you will use the device at home.
The treatment plan is outlined below.

WASHOUT PERIOD: If you are in this study and have previously been taking a cancer medicine, you will need to have what is considered a "washout period." This is a period of 2

weeks where you do not take any medicine for the treatment of your cancer. During this time, it is possible that your cancer may get worse.
Before you begin treatment, if you have not already, you will have blood drawn for clinical tests.

You will have a physical exam.

You will have tumor imaging by either a CT scan or an MRI scan to determine the size of your tumor(s). Your physician will determine which type of scan is best in your situation.

After the pre-treatment tests, you will take the cancer drug regorafenib. Regorafenib is a pill that is taken daily by mouth. You doctor will tell you how many pills to take per day.

You will also begin the TheraBionic treatments. Your first treatment will be done in the clinic.

TheraBionic is a small portable device. You will be shown how to use the device, which includes holding the metal spoons in your mouth, and you will be given an instruction manual and brochure. You may not feel the device working. Treatment with Therabionic will occur outside of the hospital/clinic (except for the very first time.) While you are receiving this treatment, you will not be able to receive other cancer treatments at the same time except for the regorafenib.

You will keep a diary of the times that you take your medicine and use the TheraBionic device (1 hour, 3 times a day, total of 3 hours) while you are on the study. In the diary, write down any symptoms that you may be having. Bring the diary with you to your study visits.

Once you start treatment you will come in for clinic visits at the following times:

Every 4 weeks
At these visits you will have a physical exam, including an oral exam, you will tell staff what medications you are taking, and have blood drawn for clinical testing. You should tell us about any side effects you are having from the treatments. Please bring your medication diaries to these visits.

If you have to stop regorafenib for any reason, for instance, for severe side effects, you can continue with the TheraBionic treatment (unless you also have severe side effects to this treatment).

Every 6 weeks (+/- 1 week)
At these visits, you will have a CT/MRI scan and a bone scan. These visits are to monitor the growth of your cancer. You would have these visits whether or not you decide to participate in the study. However, the study team will use the information that is collected at these visits for this research study.

End of study and Follow-up

Once you stop treatment, you will have an end-of-study clinic visit that will include a physical exam, determining your performance status, vital signs, and recording of any side effects. Treatment will be stopped if you experience severe side effects, if your cancer progresses, or if you decide to withdraw from the study.

Follow Up: We would like to follow up with you every 2 months for the rest of your life to determine how your health is after the study. This may be done at clinical visits or we may call you on the phone.

Blood Draws

You will have approximately 2 teaspoons of blood withdrawn from a vein before the start of your treatment, 4 weeks during treatment, and then every 4 weeks until your cancer progresses or you are no longer on the study. These blood draws are a part of your standard care and would happen even if you were not on the study. You will give an extra 2 teaspoons of blood before the start of your treatment and at one other visit for research purposes. This will be a total of about 4 teaspoons of blood for research.

CT Scans and MRI Scans

These scans are performed so that we can measure the size of your tumor(s). They are part of your standard care and will be performed before the start of your treatment and then every 6 weeks (+/- 1 week) after that point.

Diary

You will be asked to keep a diary during the study to help document the AM RF EMF treatments and any side effects you may have related to this treatment. You will need to do this daily at every treatment session for as long as you are receiving treatment.

We can send copies of your research 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. For this study, the information that may be placed in your Wake Forest Baptist medical record just for purposes of this study are: notes from the clinical study coordinator/nurse describing your participation in this study or your response and adherence to the Therabionic device and any significant side effects you might experience that could be related to your treatment with the study device and/or the combination of the study device and standard chemotherapy.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

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Study Schedule

	Pre-Study	Baseline	Phone call	Clinic Visit	Imaging	End of Treatment Visit
		(Cycle 1, Day 1)	(Cycle 1, day 15)	Week 5 and on the first day of subsequent cycles	Week 7 & every 6 weeks thereafter (+/- 1 week)	Within 30 days of withdrawal or progression
		Week 1	Week 3	Week 5	Week 7	When you withdraw, or your cancer progresses
Informed consent	X					
Regorafenib		X		X		
Ask about medications	X					X
Medical/Oncologic History and Demographics	X					
Physical Examination, including oral exam	X	X		X		X
Blood Chemistry	X			X		X
Coagulation	X					X
Pregnancy Test – (women of childbearing potential only)	X			X		X
Research Blood Studies	X					X
CT/MRI Scan	X				X	
Bone Scan	X				X	
Adverse Events Signs and Symptoms		X	X	X		X
Treatment Compliance Diary			X	X		X
Therabionic Device distributed and/or treatment logs distributed/collected		X		X		

Storage of Biological Tissue

If you agree to participate in this study, we will draw 2 teaspoons of the blood before treatment and about 2 teaspoons at a research visit to use for future research. These samples will be kept and may be used in future research to learn more about other diseases. Your sample will be obtained in the Hematology and Oncology Outpatient Clinic of Wake Forest Baptist Comprehensive Cancer Center. The sample will be stored in our Tissue Bank at Wake Forest Baptist Medical Center and it will be given only to researchers approved by Dr. Paluri. An Institutional Review Board (IRB) must also approve any future research study using your tissue 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.

The research that may be performed with your blood sample 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 will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood sample will not affect your care.

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.

The nature of the future research to be done on your blood and tissue may involve the analysis of the following: your genetic make-up, the types of proteins in your blood and tissues, the chemical and cellular processes of your tissues, and the types of components that make up your blood, cells and tissue. Your genes may be cloned for use in experiments. Your tissue may be made into living model systems. These are systems where the cells or tissue can grow on their own, when given the proper nutrients, and experiments can be performed on them. However, because of technological advancements, we cannot predict all the potential future uses for the tissues. Therefore, your tissue may be used for research projects that are not listed in this consent.

At some point in the future, we may be required to share genetic data with federal repositories. The National Institutes of Health (NIH) and other central repositories have developed special data

(information) banks that collect the results of genetic studies, especially when the research looks at all or large sections of individual's genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body. These central banks will store your genetic information and give them to other qualified and approved researchers to do more studies. The data that we share with federal repositories will be coded in such a way that you would not be able to be identified. We will not share your name, birth date, or any other information that could directly identify you. The link to the code would be kept securely at the Wake Forest Baptist Health. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

We do not think that there will be further risks to your privacy and confidentiality by sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The genetic data could be used to study a wide variety of diseases.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study until your cancer progresses, you have unacceptable side-effects, you choose to leave the study, or the study closes.

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.

WHAT ARE THE RISKS OF THE STUDY?

Risks and side effects related to the TheraBionic P1 treatment device include:

- Mild fatigue
- Mild irritation of the mouth (mouth sores) or tongue
- Vivid dreams or an increase in remembering dreams during the night.

No serious side effects have been seen, and no one has been hospitalized or died from using the treatment device. However, this is a very new kind of treatment, so you might experience new side effects, possibly even serious side effects, which have not been seen before. Experience to date suggests that use of the device is safe. However, if new risks or side effects are discovered, you will be told about them.

Given the nature of the electromagnetic fields being used, there is no known risk to others around you during the treatment.

Risks of Regorafenib:

MajorSideEffects

*****If any of the following side effects occur while taking regorafenib, check with your doctor immediately:**

- Yellowing of the skin or the white part of your eyes
- Nausea or vomiting
- Dark "tea colored" urine
- Change in sleep pattern

Other Serious Side Effects Include:

- Fever
- Severe cough with or without an increase in mucus
- Severe sore throat
- Severe bleeding-which can sometimes lead to death
- Shortness of breath
- Burning or pain when peeing
- Unusual vaginal discharge or irritation
- Redness, swelling or pain in any part of the body
- Severe bleeding
- Vomiting blood
- Pink or brown urine
- Red or black (like tar) stools
- Coughing up blood
- Unusual vaginal bleeding
- Menstrual bleeding that is heavier than normal
- Nosebleeds that happen often
- Bruising
- Lightheadedness
- Tear in your stomach or intestinal wall
- Severe pain in your stomach area
- Swelling of the abdomen
- Chills
- Dehydration
- Hand-foot skin reaction and severe skin rash- this is common and can be severe. Tell your healthcare provider right away if you get redness, pain blisters, bleeding, or swelling on the palms of your hands or the soles of your feet, or a severe rash.
- High blood pressure
- Decreased blood flow to your heart or a heart attack

- Reversible posterior leukoencephalopathy (RPLS) Call your doctor immediately if you experience a severe headache, seizure, confusion, a change in your vision, or problems thinking.
- Wound healing problems

MOST COMMON SIDE EFFECTS of Regorafenib:

•pain, including stomach-area (abdomen) •tiredness, weakness, fatigue •frequent or loose bowel movements (diarrhea) •decreased appetite •infection •voice changes or hoarseness	

•increase in certain liver function test
•fever
•swelling, pain and redness of the lining in your mouth, throat, stomach and bowel (mucositis)
•weight loss

Risks of TheraBionic without Regorafenib
In the event of regorafenib discontinuation and continued treatment with the TheraBionic device (AM RF EMF), you are potentially foregoing the benefits from other approved agents including cabozantinib, ramucirumab, nivolumab (with or without ipilimumab) and pembrolizumab.

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 Providing Confidential or Private 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.

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.

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, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, 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 diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. 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 NO method of birth control is 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 up to two 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.

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 these options:
You could receive regorafenib whether or not you participate in this research study. You could also receive another drug such as cabozantinib, ramucirumab, nivolumab (with or without ipilumumab), and pembrolizumab.

WHAT ARE THE COSTS?

All research procedures and data collection related directly to your participation in this study will be paid for by study funds and not billed to you or your insurance. These include your research blood draws, phone call follow-ups, and any drug diaries you are asked to complete. For this study, Bayer Pharmaceuticals will be providing the drug Regorafenib at no cost to you and neither you nor your insurance company will be billed for the investigational device.

All other costs for your regular medical/cancer care, which are not directly related to your participation in this study, will be billed to your insurance company or be your own financial responsibility. These include all your office visit costs, your CT and/or MRI scans, and all your routine blood labs.

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 regorafenib and TheraBionic; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. Parking for study-related visits may be provided and paid for by the 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 solely by Wake Forest Baptist Comprehensive Cancer Center and Wake Forest University School of Medicine. Bayer Pharmaceuticals is providing money and study drug to the sponsor-investigators 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 Dr. Ravi Paluri. After 5pm please ask for the physician taking calls for your treating physician.

What About My Health Information?

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected HealthInformation. The information we will collect for this research study includes**:** your health history, how you respond to study procedures, laboratory and other test results, and physical examinations, Information about your cancer treatment and medical visits.

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, as well as, Bayer Pharmaceuticals.

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 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 Dr. Paluri 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.Ravi Paluri
RadiationOncology
MedicalCenterBlvd.
WinstonSalem,NC27157

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 clinically relevant 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 it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may 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.

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 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. Ravi Paluri. After 5pm please call and ask for the physician taking calls for your treating physician.

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 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