

**CONSENT FORM****IRB PROTOCOL # 762-14-FB****Page 1 of 17****ADULT CONSENT - CLINICAL BIOMEDICAL****Title of this Research Study**

Phase II Study of Docetaxel and Capecitabine in Advanced Squamous Cell Carcinoma of the Head and Neck

**Invitation**

You are invited to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- "The Rights of Research Subjects"

**Why are you being asked to be in this research study?**

You are being asked to be in this research study because you have advanced squamous cell carcinoma of the head and neck that is either recurrent after attempted cure with surgery and radiation therapy or newly diagnosed with the disease that has spread to other parts of your body.

If you are pregnant, nursing an infant or plan to become pregnant during this study, you may not be in this study.

**What is the reason for doing this research study?**

This research study is being done to determine if this research intervention, the combination of Docetaxel and Capecitabine, is as good and not as toxic as standard of care treatment for subjects with advanced squamous cell carcinoma of the head and neck.

Though the medications used in this study are approved by the Food and Drug Administration (FDA), this combination of drugs is experimental.

About 43 people in the United States will take part in this study.

**What will be done during this research study?**

Investigators will review your medical history, current medications and previous treatment for your cancer to determine if you might qualify to participate in this research study. If you choose to sign this informed consent form, you will continue with the screening process. Many of the tests are the same as those you have had in the past to diagnose and treat your disease. Some of these same tests will also be



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done during your treatment to follow your progress.

The screening process may take place over a period of up to 2 weeks. These may take more than one visit and will include the following:

- A physical examination will be performed.
- Your actual health status and your well-being will be assessed. This is called a Performance Status Assessment.
- Blood tests to evaluate:
  - your complete blood cell count
  - your liver and kidney function
  - coagulation studies to see how well your blood clots
  - If you are female and are able to have children, a pregnancy test will be done on your blood or urine. The test must be negative for you to be in the study.
- A CT scans of the neck and chest, or MRI scans to determine the size, locations, and spread of your cancer, if they are clinically indicated and have not already been done within 4 weeks of starting study treatment.
- You will be asked to fill out a Quality of Life Assessment Questionnaire.
- You will be asked to donate a small blood sample about 6 teaspoons from your arm by standard blood drawing techniques to be frozen/stored (banked) at University of Nebraska Medical Center (UNMC).
- You will be asked to donate a small urine sample about 2 teaspoons by standard urine collection techniques to be frozen/stored (banked) at UNMC.
- You will be asked to release a portion of head and neck cancer tissue that has already been collected and saved from your surgery or biopsy for tissue banking/storage at UNMC.

If you qualify for this study and want to participate, you will start study treatment. Every subject enrolled will receive:

**Chemotherapy:** You will receive chemotherapy using the drugs, Docetaxel and Capecitabine. Docetaxel will be given intravenously over one hour on day 1 every 21 days of a 3 week cycle. You will take Capecitabine twice a day by mouth on days 1-14 every 21 days of a 3 week cycle.

Premedication for nausea may be given if needed prior to each docetaxel. Additional medications for nausea may be given as needed. You will take dexamethasone (a steroid) twice a day by mouth on the day before, the day of and the day after docetaxel.



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Every 3 weeks during chemotherapy:

- A physical examination will be performed.
- Your actual health status and your well-being will be assessed. This is called a Performance Status Assessment.
- Blood tests to evaluate:
  - your complete blood cell count
  - your liver and kidney function
- You will be asked to fill out a quality of life assessment questionnaire.
- You will be asked to fill out a medication diary for the capecitabine.

Chemotherapy therapy can lower your blood cell counts. If your blood count gets too low, the chemotherapy will need to be delayed and or reduced for your safety.

After you complete 2 cycles (6 weeks) of chemotherapy:

- You will be asked to donate a small blood sample about 6 teaspoons from your arm by standard blood drawing techniques (this will be done at the same time you have your blood drawn for your standard evaluations) to be frozen/stored (banked) at UNMC.
- You will be asked to donate a small urine sample about 2 teaspoons by standard urine collection techniques to be frozen/stored (banked) at UNMC.

After every 2 cycles (every 6 weeks) of chemotherapy:

- You will have a CT scan of the neck and chest, or MRI scans to determine the size, locations, and spread of your cancer, if they are clinically indicated. If your cancer has spread, you would no longer be eligible for this study. If your cancer has **not** spread, you will continue in the study receiving docetaxel and capecitabine as scheduled.

At the completion of the study:

- A physical examination will be performed.
- Your actual health status and your well-being will be assessed. This is called a Performance Status Assessment.
- Blood tests to evaluate:
  - your complete blood cell count
  - your liver and kidney function
- You will be asked to fill out a Quality of Life Assessment questionnaire.
- You will be asked to donate a small blood sample about 6 teaspoons from your arm by standard blood drawing techniques (this will be done at the same time you have your blood drawn for your standard evaluations) to be frozen/stored (banked) at UNMC.



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- You will be asked to donate a small urine sample about 2 teaspoons by standard urine collection techniques to be frozen/stored (banked) at UNMC.
- You will then be followed for survival and continue with follow-up visits per standard of care.

At the end of this consent form, we will ask your permission to collect and store samples of blood, urine, and tissue for future research.

### **What are the possible risks of being in this research study?**

#### **Chemotherapy**

Chemotherapy may make you feel generally unwell. This is common because chemotherapy affects good cells as well as cancer cells. Report any side effects as listed below, but continue your course of medicine even though you feel ill, unless the Investigator tells you to stop.

Chemotherapy decreases your body's ability to fight infections. Call the Investigator if you have a fever, chills, sore throat or other symptoms of a cold or flu. Do not treat these symptoms yourself. Try to avoid being around people who are sick.

Chemotherapy may increase your risk to bruise or bleed. Call the Investigator if you notice any unusual bleeding. Be careful not to cut, bruise or injure yourself because you may get an infection and bleed more than usual. Be careful brushing and flossing your teeth or using a toothpick while receiving chemotherapy because you may get an infection or bleed more easily. Check with the Investigator before you have any dental work done and tell your dentist you are taking or have taken chemotherapy.

Chemotherapy can cause nausea, vomiting and diarrhea which may lead to dehydration. Signs and symptoms of dehydration include dizziness, light headedness, fainting spells or decreased urination.

You may need to be admitted to the hospital for treatment for the side effects. Every effort will be taken to lessen side effects, but there is no way to tell which side effects may happen or how bad they may be. Unless otherwise stated, the side effects are reversible.

You will be closely monitored for any side effects you experience on the study. The investigator can give you other medications to treat the side effects or can decrease the doses of medications to stop or reduce the severity of the side effect and allow you to continue in the study.

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As with any medication, allergic reactions are a possibility.

**Docetaxel:**

The following side effects are **most common**:

- Low white blood cell
- Retaining fluid (may include swelling in hands or feet, shortness of breath)
- Nausea
- Diarrhea
- Hair loss, including face and body hair
- Feeling weak
- Low red blood cell count (anemia)
- Stopping of menstrual cycles (periods) in women
- Rash, which can be severe

These side effects are **less common**:

- Allergic reaction (fever, flushing, itching, rapid heart rate, shortness of breath, throat swelling, dizziness)
- Numbness, tingling, or pain in the hands, feet, or elsewhere
- Weakness in the hands and feet
- Sores in the mouth or on the lips
- Vomiting
- Fever
- Feeling tired
- Change in how things taste
- Loss of appetite
- Nails changing color or becoming brittle
- Skin rash
- Abnormal blood test results which suggest that the study drug is affecting your liver

(The Investigator will discuss the importance of this finding, if any.)

These side effects are **rare**:

- Low blood platelet count with increased risk of bleeding
- Redness, pain, swelling, or blisters on hands or feet (hand-foot syndrome)
- Muscle or joint pain
- Shortness of breath
- Excess tears from the eyes
- Darkening of skin where prior radiation was given (radiation recall)
- Death from infection, bleeding, or other complication
- Feeling intoxicated (confusion, stumbling, becoming sleepy)



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**Capecitabine:**

The following side effects are most **common** :

- Diarrhea (*can be very severe and life threatening*)
- Nausea
- Vomiting
- Loss of appetite
- Sores in mouth, throat, and esophagus (*these may cause difficulty in swallowing and/or heartburn*)
- Redness, swelling, pain, numbness, tingling, cracking, blistering, and peeling of the hands and feet
- Eye problems
- Tiredness
- Hair loss
- Abdominal pain
- Fever
- Constipation
- Skin problems (*rash, itching, and dryness*)
- Changes in liver function tests
- Time away from work
- Change in ability to perform activities of daily living
- Low white blood cell count

These side effects are **less common**:

- Dehydration
- Weakness
- Dizziness
- Headache
- Nail changes
- Cough
- Shortness of breath
- Depression
- Decreases in hemoglobin (the part of the blood cells that carry oxygen)
- Fever with a low white blood cell count
- Skin discoloration
- Gastrointestinal bleeding
- Mood changes
- Taste changes
- Tingling in the arms and feet (peripheral neuropathy)

These side effects are **rare**:

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- Heart problems
- Chest pain
- Low platelet count that might interfere with blood clotting
- Infection
- Changes in blood pressure
- Blood clots
- Some of these effects may be serious and life-threatening.

### Risks of Study Procedures/Tests

**CT, CAT Scans:** CT Scans involve exposure to radiation. Although the amount of radiation exposure is higher than a typical x-ray, the risk of harmful effects from a single exam is very small. The dye that is injected into a vein for the scan is usually well tolerated. Some people feel dizzy or queasy or get a headache with it or notice a cold feeling near the injection site. There is a chance of having an allergic reaction to the dye that rarely can be serious and life-threatening. The radiologist will obtain a separate informed consent explaining this procedure in specific detail.

**Drug Administration/Blood Drawing:** Some known risks, although rare, are associated with placing a needle into a vein or under the skin (when the study drug is given or when blood samples are taken). These include the possibility of infections, inflammation, a hole poked through the other side of the vein by the needle, bleeding, discomfort, pain, bruising, and a change in skin color at the site. Fainting may occur shortly after having blood collected.

- **Venous Access Device (Central Line):** In order to undergo this therapy you may need a central line. You may already have one from prior therapy. These are the risks associated with these central lines:
  - *Placement of Vascular Access Device:* The surgeon or radiologist who puts this catheter in will explain the risks in detail before he/she performs the procedure. These risks include the risks associated with anesthesia as for any operation, infection and bleeding. There may also be pain at the site where the device is inserted. Although it is rare, occasionally the lung is punctured during placement of a device and a tube must be placed in the chest to re-inflate the lung. It is also possible that there may be injury to a major blood vessel, which could lead to severe bleeding.
  - *Use of Venous Access Device:* These devices can become infected and these infections may require antibiotics, or occasionally removal of the device. It is possible for a blood clot to develop at the end of the catheter in the vein. This might prevent the catheter from working or



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rarely lead to swelling of the arm or neck and face, or to pain. Sometimes the device would need to be removed and replaced.

**Completion of the Quality of Life Questionnaire:** Rarely, people may get upset after answering questions about their symptoms and their feelings. If this happens to you, you are encouraged to discuss it with the Investigator or study nurse (Lead Coordinator) so you can receive some assistance. You may choose not to complete the questionnaire if it is too difficult for you.

**Trial Risks:**

A trial of a new combination of drugs may involve increasing risk, to a small number of participants. In studies of small numbers of subjects, toxicity may more readily become apparent through close monitoring of individual subjects. This new combination of drugs may be less effective than standard of care treatments.

**Other and Unknown Risks:**

It is possible that other rare side effects could occur which are not described in this protocol. It is also possible that you could have a side effect that has not occurred before.

**Pregnancy Risks:**

It is possible that the medicines used in this study could injure a fetus if you, or your partner, becomes pregnant while taking them. You have already been told what is known about this possibility and you are encouraged to ask further questions.

You may want to discuss this with others before you agree to take part in this study. If you wish, we will arrange for a doctor, nurse or counselor who is not part of this study to discuss the potential risks and benefits with you and anyone else you want to have present.

Because of the potential risks, you or your partner, must not become pregnant while you are participating in this study. Women must have a negative pregnancy test before entering the study.

If you are sexually active and can get pregnant or can get your partner pregnant, you must use TWO appropriate methods of birth control every time you have sex or you must not have sex.

Because of the nature of this research, methods of natural family planning are not, by themselves, sufficiently reliable to avoid pregnancy.



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You can get additional information about methods to avoid pregnancy by calling the UNMC Research Subject Advocate's Office at (402) 559-6941.

You will need to continue to avoid pregnancy for 6 months after finishing the research.

By signing this and being in the study, you are agreeing to not get pregnant while you are on the study and for 6 months after. Should you become pregnant while on this study, you should immediately notify the study personnel. The Investigator will assist you in finding appropriate medical care. The Investigator also may ask to be allowed to continue getting information about your pregnancy. You can refuse to provide this information.

### **What are the possible benefits to you?**

It is possible that this combination of drugs will be more effective and/or less toxic than standard National Comprehensive Cancer Network (NCCN) Guideline regimens.

You may not get any benefit from being in this research study.

### **What are the possible benefits to other people?**

Information obtained from this research study may help subjects in the future with the same disease by contributing to the knowledge of whether this therapy offers advantages over other therapies available.

### **What are the alternatives to being in this research study?**

If you elect not to participate in this research study, other therapy is available to you. You may choose to have standard chemotherapy alone or in combination with radiation or supportive care. You should review each of these alternatives with the Investigators and their potential benefits and risks.

### **What will being in this research study cost you?**

You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your cancer in this research study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

The study will pay for the handling of the optional research blood, urine and tissue



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sample collection and storage. The chemotherapy drugs (Docetaxel and Capecitabine) and the chemotherapy administration charges, as well as all other clinically indicated tests and procedures (laboratory tests, radiology tests, chest CT, physical examinations) will be your responsibility or your health insurance company's responsibility as these are considered standard cancer treatment. You or your health insurance company might also have to pay for other drugs or treatments that are given to help you control side effects.

You will be responsible for any applicable insurance deductibles and co-payments. If you wish to speak with a financial counselor about your insurance coverage and benefits, let the investigator or other study personnel know. A contact for personal assistance will be made available for you.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institutes Web site at:

<http://cancer.gov/clinicaltrials/understanding/insurance-coverage>

You can print a copy of the Clinical Trials and Insurance Coverage information from this Website.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

#### **Will you be paid for being in this research study?**

You will not be paid to be in this research study.

#### **Who is paying for this research?**

This research is being paid for by the Fred & Pamela Buffett Cancer Center at the University of Nebraska Medical Center.

#### **What should you do if you are injured or have a medical problem during this research study?**

Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem as a direct result of being in this study, you should immediately contact one of the study personnel listed at the end of this consent form. Emergency medical treatment for this injury or problem will be available at the Nebraska Medical Center. If there is not sufficient time, you should seek care from a local health care provider.

The Institution has no plans to pay for any required treatment or provide other

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compensation. If you have insurance, your insurance company may or may not pay the costs of medical treatment. If you do not have insurance or if your insurance company refuses to pay, you will be expected to pay for the medical treatment.

Agreeing to this does not mean you have given up any of your legal rights.

### **How will information about you be protected?**

You have rights regarding the protection and privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your research and medical records will be maintained in a secure manner.

### **Who will have access to information about you?**

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the Investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your PHI will be used only for the purpose(s) described in the section, "What is the reason for doing this research study"?

You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
  - The HHS Office of Human Research Protections (OHRP)
  - The Food and Drug Administration (FDA)
  - National Institutes of Health (NIH)
- The HIPAA Privacy Rule requires the following groups to protect your PHI:
  - Your health insurance company
  - The Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC)

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted.

You may cancel your authorization for further collection of PHI for use in this

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research at any time by contacting the Principal Investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

### **How will results of the research be made available to you during and after the study is finished?**

In most cases, the results of the research can be made available to you when the study is completed and all the results are analyzed by the Investigator or the Sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

Apar K. Ganti, MD  
987680 Nebraska Medical Center  
Omaha, NE 68198-7680

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

### **What will happen if you decide not to be in this research study?**

You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the Investigator or the Institution. The Investigator will still take care of you and you will not lose any benefits to which you are entitled.

### **What will happen if you decide to stop participating once you start?**

You can stop participating in this research ("withdraw") at any time by contacting the Principal Investigator or the Study Nurse (Lead Coordinator).

Deciding to withdraw will otherwise not affect your care or your relationship with the Investigator or this Institution. You will not lose any benefits to which you are entitled.

For your safety, please talk to the research team before you stop taking any study drugs or stop other related procedures. They will advise you how to withdraw safely.



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If you withdraw you may be asked to undergo some additional tests. You do NOT have to agree to do these tests.

Any research data obtained to date may still be used in the research.

Any tissue samples (e.g., blood, urine, tissue sample) obtained to date may also be used in the research. Should you wish to have any leftover samples withdrawn from use in future research, a request must be made in writing to the Principal Investigator at the address indicated above.

### **Will you be given any important information during the study?**

You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

### **What should you do if you have any questions about the study?**

You have been given a copy of "*What Do I Need to Know Before Being in a Research Study?*" If you have any questions at any time about this research study, you should contact the Principal Investigator or any of the study personnel listed at the end of this consent form or any study personnel listed on any other documents that you have been given.

### **What are your rights as a research participant?**

You have rights as a research subject. These rights have been explained in this consent form and in "The Rights of Research Subjects" that you have been given. If you have any questions concerning your rights or complaints about the research, you can contact any of the following:

- The Investigator or any other study personnel
- Institutional Review Board (IRB)
  - Telephone: (402) 559-6463.
  - Email: IRBORA@unmc.edu
  - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
  - Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

### **Optional Future Research on Your Blood, Urine, and Tissue**

The researchers doing this study are interested in doing additional research in the future on the blood, urine and tissue samples collected from you to better understand



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the nature of cancer and how subjects respond to treatment. Rapid advances in technology make it impossible to predict what new tests or studies may be possible in the future. Most future research studies will focus on cancer, some research projects may also include other diseases such as heart disease, diabetes or Alzheimer's disease. This may also include research on inherited traits also known as hereditary genetic testing (to find out if cancer runs in your family).

The collection of these samples before you begin treatment (research blood, urine and tissue), after you complete 2 cycles (6 weeks) and at the end of chemotherapy (research blood and urine only) is an optional part of this study. These samples will be stored at UNMC for future research projects. The samples will not be sold. The samples will be kept until they are used up or destroyed.

Reports about any research tests done with your samples will not be given to you or your oncologist, or family doctor. These reports will not be put in your medical records.

### **Risks of Donating Samples**

You may be concerned that if your personal health information (PHI) becomes available outside of the research setting, it may raise concerns with employment or insurance coverage.

To protect your identity, the information that will be on your research *tissue* samples will be limited to your pathology identification number and participant code, which may include your initials. The information that will be on your *blood and urine* samples will be limited to the participant code, which may include your initials.

These research tests are being done in a research lab, rather than the clinical lab. The results of the tests will not become part of your medical record. The results of the research tests will not be released to outside agencies such as your insurance company. Therefore, the risks of these research studies to you are small.

### **Withdrawal of Required Samples**

If you no longer want your samples to be used in this research, you should tell the Investigator. The Investigator will notify the sponsor who will ensure the samples are returned to the hospital from which they were obtained if needed, or destroyed. If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

### **Benefits**

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This research may not benefit you, but may help people in the future who have the same kind of cancer as you have.

You can indicate your wish to participate in this additional research and have your samples stored by the UNMC designated central repository for future extended research purposes when signing this consent form. You may decide not to participate in the "optional" study and still participate in this main study.

### MAKING YOUR CHOICE:

Please read each sentence below and think about your choice. After reading each sentence, check Yes or No and initial your choice. **No matter what you decide to do, it will not affect your care**. You can participate in the treatment component of the study without participating in all or part of the blood, urine, and tissue collection for future research studies.

**1. I agree to donate a small blood sample (approximately 6 teaspoons) collected up to three times during the treatment, before I start treatment at the end of 2 cycles of treatment and again at the end of treatment, to be frozen and stored (banked) at UNMC for use in future studies done here or at collaborating institutions.**

Yes

No

Initials: \_\_\_\_\_

**2. I agree to donate a small urine sample (approximately 2 teaspoons) collected up to three times during the treatment, before I start treatment at the end of 2 cycles of treatment and again at the end of treatment, to be frozen and stored (banked) at UNMC for use in future studies done here or at collaborating institutions.**

Yes

No

Initials: \_\_\_\_\_

**3. I agree to release a portion of head/neck cancer tissue that has already been collected and saved from my previous surgery or biopsy for tissue banking/storage for use in future studies done here or at collaborating institutions.**

Yes

No

Initials: \_\_\_\_\_



PT NAME:

MR#:

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### Documentation of informed consent

You are freely making a decision whether to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject \_\_\_\_\_  
Date \_\_\_\_\_

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person obtaining consent \_\_\_\_\_  
Date \_\_\_\_\_

### Authorized Study Personnel

#### Principal

\* Ganti, Apar  
phone: 402-559-8121  
alt #: 402-559-7754  
degree: MD

### Participating Personnel

* Ernani, Vinicius alt #: 402-559-8751 degree: MD	* Marr, Alissa phone: 402-559-7134 alt #: 402-559-7134 degree: MD
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* Reed, Elizabeth phone: 402-559-5749 alt #: 402-559-4000 degree: MD	* Schwarz, James alt #: 402-888-3610 degree: MD
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PT NAME:

MR#:

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\* Shonka, Nicole  
phone: 402-559-3881  
alt #: 402-559-5600  
degree: MD

## What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

**This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.**

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

**How is this research different** than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

**Make sure all your questions are answered before you decide whether or not to be in this research.**

## **THE RIGHTS OF RESEARCH SUBJECTS AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ^**

**^ to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study.** The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

**^ to freely decide whether or not to take part in the research.**

**^ to decide not to be in the research, or to stop participating in the research at any time.** This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

**^ to ask questions about the research at any time.** The investigator will answer your questions honestly and completely.

**^ to know that your safety and welfare will always come first.** The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

**^ to privacy and confidentiality.** The investigator will treat information about you carefully, and will respect your privacy.

**... to keep all the legal rights you have now.** You are not giving up any of your legal rights by taking part in this research study.

**^ to be treated with dignity and respect at all times**

**The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.**