Clinical Trials Office | Oncology and Hematology

Study Title:
A Phase II Study of Adjuvant Therapy Using a Regimen of Cyclophosphamide, Paclitaxel with Trastuzumab in Stage I-II HER2/neu Positive Breast Cancer Patients

ClinicalTrials.gov Identifier:
NCT02654119

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0318-15-FB

Sponsor / Institution:
University of Nebraska Medical Center

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ADULT CONSENT - CLINICAL BIOMEDICAL

Title of this Research Study
A Phase II Study of Adjuvant Therapy Using a Regimen of Cyclophosphamide, Paclitaxel with Trastuzumab in Stage I-II HER2/neu Positive Breast Cancer Patients

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 have been asked to participate in this study because you have recently been diagnosed with breast cancer which is confined to your breast and lymph nodes under your arm OR which is confined to your breast and not in any lymph nodes under your arm (Stage I-II breast cancer), and you have no evidence of disease elsewhere and you have not been previously treated with chemotherapy.

Although you have received surgical treatment for your cancer, there is a chance that you may have a future recurrence of the cancer in the breast, chest wall, or other parts of your body. Based on our current knowledge about the treatment of breast cancer, your doctor believes that you are a candidate for chemotherapy in order to reduce your risk of recurrence, a recommendation that is consistent with established guidelines for the treatment of your breast cancer.

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?
The reason for doing this study is to find out if the combination of cyclophosphamide and paclitaxel with trastuzumab given every two weeks results in equal effectiveness and fewer side effects.

The combination of chemotherapy drugs cyclophosphamide and paclitaxel given every 2 weeks has not been used right after surgery to keep breast cancer from reappearing. Both drugs have been approved for use as single drug therapy by the FDA for treatment of breast cancer.

About 75 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 the 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 done during your treatment to follow your progress. The screening process may take place over a period of up to 30 days. These may take more than one visit and will include the following:

- A physical examination will be performed.
- Assessment of your health status and well-being
- Blood tests to evaluate:
  - your complete blood cell count your liver and kidney function
  - 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 within 7 days of first treatment dose for you to be in the study.
- An echocardiogram to determine your heart function.
- You may have an X-ray, CT scan, or MRI if your physician deems it necessary for your care to determine the size, locations, and spread of your cancer, if they are clinically indicated and have not already been done with in 4 weeks of starting study treatment.
- Available biopsy specimens obtained at referring institutions will be reviewed for accuracy.

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

Chemotherapy: You will be treated with a combination of two chemotherapy drugs given every two weeks under the direction of a medical oncologist. This will consist of paclitaxel (T) given by vein over three hours, followed by cyclophosphamide (C) given by vein over one hour, every 2 weeks for 12 weeks (6 cycles). You will also receive pegfilgastrim (G-CSF) as a shot under the skin on the day of each cycle of CT chemotherapy, to help improve your blood counts. (If your counts adequately recover, the dose of G-CSF may be decreased or held at the treating physicians discretion on subsequent cycles.)

Appropriate premedications for nausea will be given if needed prior to each

chemotherapy treatment. Additional medications for nausea may be given as needed. You will take diphenhydramine (benadryl), ranitidine (or Pepcid if ranitidine is not available) and dexamethasone (a steroid) by mouth prior to paclitaxel.

The pathologist has determined your breast tumor contains certain proteins (Her-2 neu) that respond to the drug, trastuzumab. As a result you will be given trastuzumab along with the scheduled chemotherapy. Once the chemotherapy is complete you will continue to receive trastuzumab alone every 3 weeks for a total of 52 weeks.

Every 2 weeks during the chemotherapy:

- A physical examination will be performed.
- Assessment of your health status and well-being.
- Blood tests to evaluate:
    - your complete blood cell count
    - your liver and kidney function

When you are receiving the every 3 week trastuzumab alone, you will have these tests and physician visits at least every 12 weeks until you complete 52 weeks of trastuzumab.

Chemotherapy 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 your final treatment with chemotherapy is completed (about week 12), radiation and hormone therapy may be added if your physician thinks it is clinically indicated for your care. The timing of the radiation and hormone therapy in relation to each other will be determined by your radiation and medical oncology team as deemed appropriate for your type and stage of breast cancer.

After your final treatment with chemotherapy is completed, you will have a follow-up echocardiogram to monitor your heart function. You will continue to have a follow-up echocardiogram every 12 weeks for the duration of the trastuzumab.

Additional follow-up care will include a physical exam; other tests may be done as requested by the physician as indicated every 3 months for two years after your diagnosis then every 6 months until you are five years from diagnosis, or until disease recurrence. Participation in this long term follow-up is needed to evaluate the long term safety and efficacy of the therapy.

You will be asked to keep a current address and phone number on file as part of this

long-term follow-up. Should you move, please contact one of the individuals listed at the end of this consent form to update your contact information.

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.

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, lightheadedness, 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.

As with any medication, allergic reactions are a possibility.

Cyclophosphamide:

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

- Low white blood cell count with increased risk of serious infection
- Retaining fluid (may include swelling in hands or feet, shortness of breath)

- Nausea and/or vomiting
- Diarrhea
- Hair loss, including face and body hair
- Feeling weak
- Low red blood cell count (anemia)
- Low blood platelet count with increased risk of bleeding
- Stopping of menstrual cycles (periods) in women
- Ovarian damage (ability to have children may be permanently impaired)
- Rash, which can be severe
- Loss of appetite
- Ulcers
- Bladder irritation and/or pain
- Appearance of blood in the urine
- Scarring of the bladder
- Metallic taste during injection

These side effects are **rare:**

- Very rarely, scarring of the lungs
- Coughing spells
- Shortness of breath
- Heart failure
- Develop a second cancer (i.e. leukemia)
- Temporary hair loss
- Headache
- Dizziness
- Yellowing of the skin
- Allergic reaction (fever, flushing, itching, rapid heart rate, shortness of breath, throat swelling, dizziness)
- Abnormal blood test results which suggest that the drug is affecting the liver
- Discoloration of the skin and nails

Paclitaxel:

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

- Low white blood cell count with increased risk of serious infection
- 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
- 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 drug is affecting the liver

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)
- Unsteadiness when walking
- Lightheadedness
- Dizziness
- Headache
- Loss of reflexes
- Sensation of flashing lights and blurred vision
- Cranial nerve paralysis, seizures and death.
- Irregular heartbeat
- Slowing of the heart rate
- Fluid accumulation around the heart
- Rarely, serious and life threatening abnormal heart rhythms
- Flu like symptoms (headache, muscle aches, joint pain, low back pain, tiredness, drowsiness and weakness)
- Fever

Pegfilgrastim (G-CSF):

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

- Temporary, mild to moderate bone pain (aching sensation in the bones of the back, hips, pelvis or breast bone)
- Nausea
- Diarrhea
- Vomiting
- Fever
- Fatigue
- Flu-like symptoms.
- Skin rash
- Lack of appetite
- Headache
- Cough
- Chest pain
- Generalized weakness
- Decrease in liver and kidney function
- Burning sensation, redness, pain and bruising at the injection site

Trastuzumab:

- Allergic/hypersensitivity reaction with a fast heart rate, wheezing, low blood pressure, sweating, itching and a face rash may happen within a few minutes of treatment.
- Death due to hypersensitivity reaction has happened.
- Flu like symptoms (headache, muscle aches, joint pain, low back pain, tiredness, drowsiness and weakness)
- Diarrhea
- Changes in kidney function
- Heart failure
- Painful breathing or increased cough
- Fluid accumulation around the heart
- Rarely, serious and life-threatening abnormal heart rhythms and heart attacks have occurred.

Risks of Study Procedures/Tests

Echocardiogram: The echocardiogram uses sound waves to measure the pumping function of the heart and does not pose any additional risk.

X-RAY/CT, CAT Scans: X-rays and CT Scans involve exposure to radiation. The risk of harmful effects from a single exam is very small. The dye that is injected into a vein for the CT 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.

Magnetic Resonance Imaging (MRI): The magnetic resonance imaging (MRI) machine is a powerful magnet. This magnet may cause any metal in the body to move. If you know of any metal in your body, you will need to tell the staff. If you suffer from claustrophobia, fear of closed spaces, you may find the MRI equipment too confining. In that case, you can request to be removed form the scanner and this will be done immediately. You may feel uncomfortable from lying on the hard surface of the MRI table. The MRI makes loud noises when scanning, so you will be given ear muffs to wear.

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. 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 rarely lead to swelling of the arm or neck and face, or to pain.

Sometimes the device would need to be removed and replaced.

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.

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 the combination and timing of drugs used in this study may be more effective and/or less toxic than the standard chemotherapy treatments.

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

What are the possible benefits to other people?
Information obtained from this 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 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 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 sample collection and storage. The drugs (cyclophosphamide, paclitaxel, pegfilgrastim, and trastuzumab) and the drug 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 people 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 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 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:
Pavankumar Tandra, MD
987680 Nebraska Medical Center
Omaha, NE 68198-7680

A description of this clinical trial will be available on 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. Your doctor 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 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. 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 (e.g., blood sample) obtained to date may also be used in the research. Should you wish to have any leftover tissue 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 study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or 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 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
The researchers doing this study are interested in doing additional research in the future on the blood samples collected from you to better understand 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).

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about

health and disease. If you agree to take part in this tissue bank and your samples are used in future NIH sponsored genetic research, some of your genetic and health information will be placed into a scientific database that is maintained by the NIH. A researcher who wants to study the genetic information must apply and be approved to use the database. Researchers with an approved study may be able to see and use your information (along with that of many other people), but your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. As your genetic information is unique to you, however, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your information confidential.

The collection of these samples before you begin treatment (research blood), after you complete 6 cycles (12 weeks) and at the end of treatments (52 weeks) is an optional part of this study, these samples will be be stored at UNMC for future research projects. 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* 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 the 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
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 collection for future research studies.

1. I agree to donate a small blood sample (approximately 3 tablespoons) collected up to three times during the treatment; before I start treatment at the end of 6 cycles of treatment, and again 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: _____

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
* Tandra, Pavan kumar (Pavan kumar)
alt #: 402-559-4000
degree: MD

Secondary
* Cowan, Kenneth
alt #: 402-559-4000
degree: MD

* Krishnamurthy, Jairam
alt #: 402-888-1531
degree: M.D.

* Reed, Elizabeth
alt #: 402-559-4000
degree: MD

Other Coordinator
Mailliard, Mary
alt #: 402-888-2123
degree: RN

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.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

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.