University of Nebraska Medical Center
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Clinical Trials.Gov PRS Cover Sheet

Official Title: Phase I/II study to assess the safety and efficacy of consolidative hypofractionated radiation therapy (hfRT) for boosting the residual primary lung cancer in combination with Durvalumab after definitive chemoradiation therapy for stage III non-small cell lung cancer (NSCLC)

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CONSENT FORM

Title of this Research Study

Phase I/II study to assess the safety and efficacy of consolidative hypofractionated radiation therapy (hfRT) for boosting the residual primary lung cancer in combination with Durvalumab after definitive chemoradiation therapy for stage III non-small cell lung cancer (NSCLC)

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

Purpose

We are doing this study to learn if it is safe to add two boost radiation doses. The boost radiation is added with durvalumab after standard cancer treatment. Boost radiation increases the amount of radiation you receive.

Methods

You will receive durvalumab with the boost radiation after completing standard cancer drug treatment and radiation. Durvalumab is started within four weeks after standard cancer treatment is complete. You will receive durvalumab for one year.

After you finish your study treatment, the investigator will continue to follow you according to standard follow up schedule.

Side Effects

Very common side effects when taking durvalumab include: feeling tired, nausea, vomiting, diarrhea, excess fluid causing swelling, upper respiratory tract infections, shortness of breath, cough and fever. Other side effects are rash/dry itchy skin, and liver problems. Some side effects can be very serious and life-threatening and may even result in death.

Common side effect of radiation include: swelling and redness in the area of radiation, cough, shortness of breath, painful swallowing, hair loss, bleeding and bruising and rib pain.

Benefits
Adding the radiation boost while taking durvalumab may increase the time until your disease worsens compared to not adding the boost radiation.

Alternatives to the study
You may receive durvalumab alone as treatment after you receive regular cancer treatment and radiation. The researcher will talk to you about the options.

If you do not wish to be in the study, your doctor can help you decide on the best treatment available to you.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are diagnosed with non-small cell lung cancer (NSCLC). You can be in the study if you are scheduled to begin definitive chemotherapy and radiation treatment (dCRT) or you have already completed dCRT and two cycles of platinum-based cancer treatment.

This study will be open to subjects at UNMC only. We plan to enroll 43 participants taking part in this study.

What is the reason for doing this research study?
The purpose of this study to learn if adding two boost radiation treatments and one year of durvalumab therapy for your type of lung cancer is safe and useful. The two boost radiation treatments will be completed after standard radiation therapy and chemotherapy for your lung cancer.

Durvalumab is an antibody (a protein produced by the body's defense system) and it is hoped this antibody can activate the immune cells in the body. This activation may be able to prevent or slow down cancer growth. Durvalumab is FDA approved for treating stage III non-small cell lung cancer after completing chemotherapy and radiation. It is not FDA approved for use at the same time as boost radiation. Boost radiation therapy is considered safe for patients when used alone.

What will be done during this research study?

If you decide to take part in this study, you will receive durvalumab and two boost doses of radiation. You will receive the durvalumab with the boost radiation after completing standard cancer treatment of chemotherapy and radiation over a six week period. You will receive durvalumab through your veins starting within four weeks after standard radiation and chemotherapy for one year. You will receive durvalumab every two weeks. If the investigator decides that additional radiation therapy is possible then two more radiation doses (called boost radiation doses) will be given. The boost radiation will be given between the second and third doses of durvalumab.

After you finish your study treatment, the investigator will continue to follow your condition for another year (for a total of three years of participation in this study) and watch you for side effects. After this time, your treating physician will discuss usual care options and follow up for your cancer.

Everyone taking part in this study will get the same dose of durvalumab. To make sure that the boost radiation can be given safely with durvalumab, small numbers of subjects will be given a low dose of boost radiation. The side effects of the combination treatment will be noted. If the boost radiation is tolerated, then the next group of subjects will receive a higher dose. The dose of boost radiation depends on when you enter the study. You will only receive two doses of boost radiation, given every other day.

Before you begin the study, the investigator will review the results of your exams, tests, and procedures. This helps the investigator decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are tests that will be done for research purposes only.

- Safety labs to make sure durvalumab continues to be safe for you
- Electrocardiogram, to make sure your heart is healthy enough to take durvalumab
- The two boost radiation doses
- Optional Tumor biopsy, this biopsy is done approximately 2 months after the boost radiation doses are completed

Standard cancer treatment of chemotherapy and radiation Period

If you choose to take part in the study, you may begin before you start standard

cancer treatment of chemotherapy and radiation. During this period all clinical procedures are part of your standard care. We will watch you for any side effects you may have to the standard treatment. Also, we will ask to collect research blood samples as the times indicated below. An optional PD-L1 testing sample collection for assessment. The testing will be done on your prior biopsy used to confirm your diagnosis. PD-L1 is a signal that may be stopping the body's immune system from killing the cancer.

Durvalumab with Boost Radiation period
Within 42 days (six weeks) of completing standard cancer treatment with radiation you will start durvalumab dosing.

Screening
Before starting durvalumab, you will complete the following assessments to make sure you are eligible to continue.

- Physical exam with vital signs
- Medical history with cancer performance assessment
- Electrocardiogram, to measure activity of your heart
- Blood draw for routine tests, which include a hematology lab and a chemistry lab. These are done to make sure your blood and organs are okay.
- Blood pregnancy test if you are female and are able to bear children
- Urine sample for routine tests
- Optional PD-L1 testing sample collection from a prior biopsy
- Your tumor will be assessed by one of the following imaging methods: Computerized tomographic (CT) scan of the chest, abdomen, and pelvis, positron emission tomography (PET) scan or MRI (magnetic resonance image) with an intravenous (IV) injection of contrast dye.
- Quality of Life questionnaire will be done, which will ask you how are feeling physically and emotionally. If any question makes you uncomfortable, you may skip those questions and not give an answer.

If you are eligible to continue, then just before the first and second dose of durvalumab, the following assessments will be done:

- Physical exam and cancer performance assessment
- Vital signs
- Blood draw for routine tests, which include a hematology lab and a chemistry lab. These are done to make sure your blood and organs are okay.
- Blood pregnancy test if you are female and are able to bear children
- Quality of Life questionnaire will be done, which will ask you how are feeling physically and emotionally.

Study Drug - durvalumab
You will get durvalumab through a vein in your arm every two weeks. This will begin about one month after you complete the standard chemo- and radiation therapy. Durvalumab will be given for up to one year or until you have serious side effect or your cancer gets worse. If at one year your cancer is still controlled as assessed by MRI or CT scan, then durvalumab may be re-started. You may receive durvalumab an additional 12 months.

Prior to each durvalumab dose (every two weeks):
Each time you come to the study center for durvalumab, the following will be performed:

- Physical exam and cancer performance assessment
- Vital signs
- Blood draw for routine tests, which include a hematology lab and a chemistry lab. These are done to make sure your blood and organs are okay.
- Blood pregnancy test if you are female and are able to bear children

Approximately 2 months after the boost radiation doses, there is an optional Tumor biopsy.

We will assess your tumor by imaging within one month of durvalumab re-starting. You will be assessed again every 12 weeks (**± 2 weeks)** while on durvalumab. At the same time of your imaging visits, you will be asked to complete the Quality of Life questionnaire.

Tissue Sample
The investigator will need to use some of the tissue leftover from your biopsy when you were diagnosed with cancer. This sample will be used to test your cancer cells for the presence of markers that may help the immune system fight cancer.

Research Blood Samples
Several blood samples will be collected for research purposes. If you start the study before you start cancer treatment (chemotherapy and radiation), we will collect samples at the following time points.

- During the screening period
- Before the 6th dose of radiation
- Before the 16th dose of radiation
- Within 72 hours of your last dose of radiation

Additional samples are collected after completing the standard cancer treatment also.

If you start the study at this time, then we will collect samples at the following time points.

- Within 24 hours of the planning day for the boost radiation doses, but before the required CT scan is completed
- Same day as the first boost radiation dose, before the dose is given
- Same day as the second boost radiation dose, before the dose is given
- Within 24 to 72 hours after the second boost dose, but before the next cycle of durvalumab;
- At each follow up visit, every 8 weeks for the first year; every 12 weeks for the second year.

At each time point about 1 tablespoon of blood will be collected from a vein in your arm. Researchers will study cells in your blood that carry components from your primary tumor.

The sample(s) we collect will not be used for other research studies by us, or by any other investigator after this research is over.

There are no plans to perform any genetic tests (including whole genome sequencing) on your samples.

What are the possible risks of being in this research study?
If you choose to take part in this study, there is a risk that the durvalumab plus radiation may not be as good as the usual approach for your cancer at shrinking or stabilizing your cancer.

The study drug durvalumab works by boosting the immune system. This may cause side effects, which can occur when the drug is given or after the drug is given (within hours, days or weeks after). Some side effects usually get better without any treatment. However, some side effects may become serious or life-threatening and have resulted in death who have received treatment with durvalumab. It is important to tell your study doctor immediately if you have any side effects so that you can receive the necessary treatment.

<u>Study drug - durvalumab</u>
The study drug may cause side effects. You may experience none, some or all of those listed below.

Most of the possible side effects listed below are mild to moderate. However, some side effects can be very serious and life-threatening and may even result in death.

Some side effects do not need treatment while others generally get better with treatment. Some patients may need to delay doses of durvalumab to allow the side effects to get better. The most important possible side effects, which are listed below, may occur because of the way durvalumab works on the immune system and they have been seen with durvalumab in clinical studies. Side effects like these have also been seen in clinical studies with other drugs that are very similar to durvalumab.

Very common side effects in cancer patients (affect more than 1 in 10 patients) treated:

- feeling tired,
- nausea, vomiting,
- abdominal pain,
- excess fluid causing swelling
- upper respiratory tract infections,
- decreased appetite
- shortness of breath,
- cough and,
- fever
- Diarrhea
- Rash/dry itchy skin
- Liver problems: Increases in the blood level of substances called enzymes found within your liver cells may occur. The enzyme changes are unlikely to make you feel unwell. However if these blood enzyme levels become very high, your study doctor may need to stop the study medication. Signs and symptoms of elevated enzymes are:
    - yellowing of the skin or whites of the eyes,
    - dark urine,
    - severe nausea and vomiting,
    - pain in the upper right side of your abdomen,
    - skin itchiness,
    - not feeling hungry and
    - bleeding or bruising more easily than normal

Common side effects (affects between 1 in 100 up to 1 in 10 patients)

- Inflammation in the lungs
- Low thyroid activity
- High thyroid activity
- Kidney problems
- Nervous system problems
- Infusion Related Reactions

- Inflammation of the intestine (colitis)

Additionally, common side effects for cancer patients treated on clinical trials:

- a hoarse voice,
- painful urination,
- night sweats,
- pneumonia,
- oral thrush,
- dental and oral soft tissue infection,
- pain in muscles and joints and,
- influenza

Uncommon side effects (affects between 1 in 1,000 to 1 in 100 patients)

- Inflammation of the pancreas (pancreatitis)
- Allergic reactions
- Problems with your adrenal glands
- Problems with the pituitary gland
- Inflammation of the muscles or tissues, such as blood vessels that supply the muscles

Rare side effects (affects between 1 in 10,000 to 1 in 1,000 patients)

- Type 1 Diabetes mellitus which may cause increased blood glucose levels
- Problems with the pituitary gland
- Inflammation of the heart muscle

Additionally, rare side effects for cancer patients treated on clinical trials:

- inflammation of the membrane surrounding the heart,
- growths of tiny collections of inflammatory cells in different parts of the body (a condition called sarcoidosis) that can be treated with steroids,
- inflammation of the middle layer of the eye and other events involving the eye,
- hardening and tightening of the skin and connective tissues and loss of skin color), and
- abnormal breakdown of the red blood cells and low levels of platelets,
- inflammatory disorder causing muscle pain and stiffness and autoimmune arthritis
- Diabetes insipidis - a condition in which your kidney can't concentrate urine
- inflammation of the brain

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 and before each durvalumab treatment dose.

If you are sexually active and can get pregnant, or can get your partner pregnant, you must use ONE highly effective appropriate method 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 180 days after the last dose of durvalumab only infusion.

For men: Do not father a baby while taking part in this study. Men must use an adequate method of contraception to avoid pregnancy for the duration of the study and 180 days after the last dose of study drug.

By signing this and being in the study, you are agreeing to not get pregnant while you are on the study and for 180 days after the last dose of durvalumab. 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.

Possible Side Effects of Lung Radiation

Common (In 100 people receiving lung radiation, more than 20 and up to 100 may

have):

- Swelling and redness, tanning, thickening, numbness, or peeling of the skin in the area of radiation
- Difficulty and/or pain with swallowing
- Hair loss in the treatment area, may be permanent
- Shortness of breath
- Cough with or without increased phlegm production
- Tiredness
- Diarrhea, nausea
- Anemia, which may require blood transfusion
- Infection, especially when white blood cell count is low
- Bleeding, bruising
- Rib pain, increased risk of rib fracture

OCCASIONAL, SOME MAY BE SERIOUS (In 100 people receiving lung radiation, from 4 to 20 may have):

- Inflammation of the lung that may cause difficulty breathing and can be life-threatening
- Narrowing of the throat which may cause vomiting, difficulty swallowing
- Scarring in the lung
- Lung collapse
- Fluid around lungs
- Bleeding from the lungs which may cause coughing up blood
- Fever
- Narrowing of the esophagus
- Pain in chest wall

RARE, AND SERIOUS (In 100 people receiving lung radiation, 3 or fewer may have):

- Abnormal opening in internal organs which may cause pain and bleeding
- Irritation of the heart causing heart failure, heart attack, chest pain, abnormal heartbeat, shortness of breath, swelling of ankles, cough or tiredness
- Transverse myelitis irritation of the spinal cord causing weakness, tingling or numbness of the lower body and legs, or paralysis of the lower half of the body
- Brachial plexopathy irritation of the nerves controlling the arm, causing weakness or paralysis
- Bleeding from the airway (windpipe)
- Narrowing of the airway causing shortness of breath
- Death
- Lung damage, may be life threatening

- Damage to the large blood vessels surrounding the heart, which could cause coughing up of blood and possibly death
- Sores and skin damage causing bleeding and severe pain and may lead to an open wound

What are the possible benefits to you?
It may be possible that adding radiation boost while taking durvalumab may increase the time until your disease worsens compared to not adding the boost radiation. It is possible your cancer will not improve during the study or may even worsen. There may be risks involved in taking this drug that have not yet been discovered.

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

What are the possible benefits to other people?
The study may help the study doctors learn things that may help other people with lung cancer in the future.

What are the alternatives to being in this research study?
If you decide to take part not to take part in this study, you may receive durvalumab alone as a maintenance treatment after you receive regular cancer treatment and radiation.

What will being in this research study cost you?
You will not be responsible for any research-related costs.

You will have to pay any insurance deductibles and co-payments. If you want to speak with someone about your insurance, just tell us.

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?
AstraZeneca Pharmaceuticals gives us money to do this study.
Dr. Apar Ganti, participating personnel on this study, receives money for providing consult services for Astra Zeneca, the sponsor of this study.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical

problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.

We have no plans to pay for your treatment or give you any other money or compensation. Your insurance may pay. If they do not you will have to pay.

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

How will information about you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.

The information will not be used for other research by us, or by any other researcher.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

We may share your PHI with other groups listed below. The HIPAA Privacy Rule

requires these groups to protect your PHI.

- The Food and Drug Administration (FDA)
- Your health insurance company
- The Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC)

We may share your PHI with other groups listed below. These groups are NOT required by HIPAA to protect your PHI. If we share your PHI with these other groups they may share it with others who also do not have to protect it under HIPAA.

- AstraZeneca, which provides fund for this research and may pay the Organization to do this research
- The Data and Safety Monitoring Committee (DSMC)
- The National Cancer Institute's (NCI) Clinical Trial Reporting Program

You are letting us use and share your PHI for as long as the research is going on.

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 Ganti, MD
986840 Nebraska Medical Center
Omaha, NE 68198-6840

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

organization. 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 being in this research (withdraw) at any time. Just call the researcher or any research staff

If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. 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 research medicine or treatments. They will tell you how to do it safely. They may ask you if you will have some extra tests. You do NOT have to agree to do these tests.

You may be taken off the study if you do not follow instructions of the investigator or the research team.

You may also be taken off the study if:

- you have side effects from durvalumab before starting boost radiation that in the opinion of the investigator indicates you should not get the boost radiation
- you become pregnant or intend to become pregnant
- you have side effects after the first boost radiation fraction that in the opinion of the investigator indicates you should not get the second fraction
- you start to take another anti-cancer therapy, including another investigational drug
- confirmation of progressive disease that indicates taking durvalumab would not benefit you
- confirmation of progressive disease before the boost radiation that indicates taking durvalumab or durvalumab with radiation would not benefit you

Any research data we have already collected can still be used in the research.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"*

If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

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 want to discuss problems, concerns, obtain information or offer input, or make a complaint 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 PD-L1 testing and Tumor biopsy sample collection
You may take part in these additional studies if you want to. You can say "yes" or "no" to these options. You can still be a part of the main study even if you say 'no' to taking part in this additional study. Please mark your choice with your initials.

The researchers doing this study are interested in doing additional research now on samples collected from you to better understand the nature of lung cancer.

The collection of the tumor tissue samples occurs as part of your clinical care. We are asking if you are willing to have the tissue used for PD-L1 testing. Also, if you agree we would like to do an extra tumor biopsy approximately 2 months after the boost radiation doses are complete. This tumor biopsy would be done only for research purposes.

The samples will not be sold. 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.

Confidentiality of Samples
To protect your identity, the information that will be on your blood samples will be

limited to the participant code, which may include your initials. The samples may possibly be traced back to you, but we will take steps to protect your confidentiality.

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 ensure that the samples are 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.

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 collected and tested when you sign this consent form. You may decide not to take part in the optional study and still take part in the main study.

Archive tumor tissue (from initial diagnosis) for immunohistochemistry testing (including PD-L1):

_____ You agree to allow PD-L1 testing on your archived tumor tissue (optional).

_____ You do not agree to allow PD-L1 testing on your archived tumor tissue (optional).

Research tumor biopsy:

_____ You agree to have an extra tumor biopsy at 2 months after the boost radiation doses for research (optional).

_____ You do not agree to have an extra tumor biopsy at 2 months after the boost radiation doses for research (optional).

Documentation of informed consent
You are deciding whether to be in this research study. Signing 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.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.

- 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
* Abughanimeh, Omar
phone: 402-559-8013
alt #: 862-276-9863
degree: MBBS

* Baine, Michael
phone: 402-552-2703
alt #: 402-552-3844
degree: MD, Ph.D

* Bennion, Nathan
alt #: 402-552-2247
degree: MD

* Lin, Chi
phone: 402-552-3844
alt #: 402-552-3879
degree: MD, Ph.D

* Marr, Alissa
phone: 402-559-7134
alt #: 402-559-7134
degree: MD

* Sharma, Bhavina
phone: 402-559-5692
alt #: 402-559-5692
degree: MD

* Zhen, Ken (Ken)
phone: 402-552-2038
alt #: 402-552-2038
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.

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.