ADULT CONSENT - CLINICAL BIOMEDICAL

Title of this Research Study

A Phase 1/2 Trial for Patients with Newly Diagnosed Anal Cancer Treated with Concurrent Radiation Therapy, 5FU, Mitomycin and BMX-001

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 take part in this research because you have newly diagnosed locally advanced anal squamous cell carcinoma (SCC) (including oligometastatic disease; your metastasis is not widespread); and you will be receiving concurrent chemoradiation with standard 5FU/Mitomycin regimen with curative intent.

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 study will use an investigational drug called BMX-001. Investigational means that the study drug has not been approved by the U.S. Food and Drug Administration (FDA) for sale in the United States and will not be approved until studies show that the study drug is not harmful and has good results. BMX-001 is an investigational drug that is being tested to determine the impact it may have on lessening the side effects of standard chemotherapy and radiation treatment for your cancer. BMX-001 is a new class of compound that would be termed a redox-active metalloporphyrin. This drug was designed to mimic the body's most powerful antioxidant enzymes and is a potent anti-inflammatory that acts by blocking multiple steps in the inflammatory cascade. By inhibiting the inflammatory cascade BMX-001 is expected to protect normal tissues from the inflammatory side-effects of radiation and chemotherapy while at the same time acting as an antioxidant that will have an inhibitory effect on the growth of tumor.

Current standard treatment for SCC anal cancer is radiation therapy and chemotherapy (infusional 5FU and mitomycin). Previous research has determined that radiation combined with 5FU and mitomycin provides the best local control of

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disease and long-term survival rates. However, there are significant side effects from treatment. Radiation and chemotherapy can harm healthy tissue surrounding the area of cancer. BMX-001 is currently being studied in human subjects in other cancers such as: with head and neck cancer, primary brain cancer, and with other cancers that have metastsized to the brain.

The main purpose of this study is to test the safety and effectiveness of BMX-001 at various dosages. BMX-001 is given by injection under the skin (in the abdomen, upper arm, or upper leg) twice a week for approximately 7 weeks (during radiation therapy).

About 26 people will take part in this study at Nebraska Medicine.

What will be done during this research study?
Before you begin the study:
If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure you are eligible.

- History and physical exam which will include recording medications you are taking, vital signs, height and weight
- Symptom assessment questionnaires (rectal, gastrointestinal, urinary, and skin)
- Blood draw (by needlestick) for hematology (blood counts), blood chemistry and blood clotting ability, pregnancy test, (if you are female of childbearing potential)
- Blood will be collected to measure oxidative stress; which may be increased in cancer and contribute to tumor growth. This will be measured throughout your treatment with BMX-001 to study the relationship of BMX-001 and oxidative stress.
- MRI and PET Scans
- Electrocardiogram (ECG)
- Evaluation of your ability to carry out daily activities
- Assessment of Quality of Life (used to evaluate the general well-being of individuals) and gastrointestinal (GI) specific assessments of symptoms related to anal cancer. The survey is given on a small touch screen computer. You may be familiar with this type of computer. Similar computers are used in bank machines, airport check in lines, and at gas stations. Your answers to the survey will not be available to your doctor or medical staff, will not be part of your medical record. The answers to the questionnaires will be available to the study staff. The information will help doctors understand what factors affect response to treatment.

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- Colonscopy or Anoscopy (if this was done prior to this study it will not be repeated)

During the Study:
If the exams, tests, and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. Some are part of regular cancer care.

During treatment:

- A physical examination including vital signs and weight measurement will be done weekly
- Information regarding medications you are taking will be reviewed weekly
- Blood tests (about 3 teaspoons of blood will be taken from your vein) (weekly)
- Evaluation of any side effects from treatment you may be having (weekly)
- Symptom assessment questionnaires (rectal, gastrointestinal, urinary and skin) (weekly)
- Radiation therapy and chemotherapy (5FU and mitomycin) according to the standard of care guidelines. Your doctors will discuss specifically the treatment regimens for radiation and chemotherapy.
- BMX-001 will be given twice a week during radiation therapy (this is typically on Mondays and Wednesdays but that could change). BMX-001 will be injected under your skin (on your torso, upper leg, or upper arm).
- ECG(Electrocardiogram) (the day you first receive the study drug, the second day you receive it in week 1 and in week 4). These will be done before you receive the study drug and at about one hour after you receive it.
- Pharmacokinetics (PK) sampling (weeks 1, 2,4 and 6) or blood tests will be collected for analysis. This analysis explores what your body does to the drug; whether it is absorbed, chemically changed in the body (e.g. by enzymes), and how it is excreted or eliminated. The first 9-12 subjects enrolled will participate in the additional pharmacokinetic (PK) blood tests. Please speak with a member of your study team to determine if you are one of these subjects.
- Quality of life questionnaires (will be completed weeks 2,4,6 during radiation)

You will need these tests and procedures in follow-up visits:
These tests and procedures are being done to see how you and your cancer was affected by the treatment you received as well as evaluation of any treatment related side effects.

At about 1 month after you finish treatment:

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- A physical examination including vital signs and weight measurement
- MRI
- Questionnaires (symptom and Quality of life)
- Information regarding medications you are taking
- Evaluation of your ability to carry out daily activities
- Blood tests (hematology and blood chemistry)
- Blood will be collected to measure oxidative stress
- Evaluation of any side effects from treatment you may be having

At about four months and ten months after you finish treatment:

- A physical examination including vital signs and weight measurement
- PET/CT (month 4 or a different time if instructed by your doctor)
- Questionnaires (symptom and quality of life)
- Information regarding medications you are taking
- Evaluation of your ability to carry out daily activities
- Blood tests (hematology and chemistry)
- Blood will be collected to measure oxidative stress (month 4 only)
- Evaluation of any side effects from treatment you may be having
- Colonoscopy or Anoscopy at about 10 months and 24 months after you complete radiation treatment.

The tests during screening and throughout the study are explained in more detail below:

Blood Tests: In total, approximately 4 teaspoons (20 mL) of blood will be drawn from your arm by a needlestick for the evaluations before starting the study drug during the screening period. These blood tests done at screening will include a complete blood count (CBC), blood chemistry (CMP) and tests of how well your blood clots (PT/aPTT). During the course of the study, complete blood count (CBC) tests and blood chemistry (CMP) tests will be drawn weekly (approximately 3 teaspoons) while you are receiving radiation therapy beginning at Week 1. Following the cessation of radiation therapy, complete blood count (CBC) and blood chemistry (CMP) tests will be drawn (3 teaspoons) at approximately one month, four and ten months after radiation therapy.

For women of childbearing potential, a blood test to rule out pregnancy will be done during the screening period within 48 hours prior to starting the study drug. Approximately 1 teaspoon of blood will be taken to perform this test.

Pharmacokinetic tests (PK's): Blood will be drawn for (PKs) on the first day the

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study drug is given, week 2 of radiation therapy, week 4 and week 6 of radiation therapy for up to 12 patients enrolled in this study. PKs measure the way that your body absorbs and distributes the study drug, BMX-001. On the first day of a PK analysis, you will have 4 blood draws, one before receiving BMX-001 and then one 30 minutes after, 4 hours after and 24 hours after receiving BMX-001. Each blood draw is slightly less than 1 teaspoon (3 mL) of blood, for a total of almost 21/2 teaspoons (12 mL) on each of the PK analysis periods.

Magnetic resonance imaging (MRI) is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. This is done as part of the standard of care for your cancer treatment.

Positron emission tomography (PET) is a test that uses a special type of camera and a tracer (radioactive chemical) to look at organs in the body. The tracer usually is a special form of a substance (such as glucose) that collects in cells that are using a lot of energy, such as cancer cells. This is done as part of the standard of care for your cancer treatment.

Electrocardiogram (ECG): ECG is a diagnostic tool that is routinely used to assess the electrical and muscular functions of the heart. This will be done before and after receiving study drug on the first day you receive the study drug, at week one and also at week four.

Questionnaires: Quality of life will be assessed by using patient report outcomes (PROs). Also, you will report of your symptoms (rectal, GI, GU, perianal skin), concerns, and feelings. This will be evaluated using questionnaires. These questionnaires will ask questions about your overall well-being, mood, thoughts, feelings, physical function and thinking.

Blood collection for oxidative stress studies: Oxidative stress is associated with increased production of oxidizing species or a significant decrease in the effectiveness of antioxidant defenses. Oxidative stress markers are known to increase from radiation. Blood will be collected to determine the effects of BMX-001 on oxidation caused by radiation.

Colonoscopy is an exam in which your doctor inspects the inside of your colon with colonoscope, a long, flexible, tubular instrument about 1/2-inch in diameter that transmits an image of the lining of the colon so the doctor can examine it for any abnormalities. The colonoscope is inserted through the rectum and advanced to the

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other end of the large intestine.

Anoscopy is an examination using a small, rigid, tubular instrument called an **anoscope** (also called an anal speculum). This is inserted a few inches into the anus in order to evaluate problems of the anal canal. You physician will order one or the other exam not both.

Additional tests may be done at the discretion of your physician as part of your regular care throughout the study. These exams and tests will be done to monitor the effects of study drugs.

HOW LONG WILL I BE IN THIS STUDY?

You will receive the study drug, BMX-001 from four days up to one hour before you start radiation therapy and for the approximately 6-7 weeks of your radiation therapy. You will then be followed on this study for two years. Thereafter, you will continue to receive routine care as determined by your treating physician. Patients can receive study treatment as long as there is no evidence of progression of your cancer or unacceptable toxicity (side effects). The study doctor may also take you off the study if new scientific developments occur that indicate the treatment is not in your best interest, or he/she feels that this treatment is no longer in your best interest.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

The initial study visit and the study visits at the end of your radiation therapy and at 1, 4 and 10 months post radiation therapy will take approximately 2 additional hours to fill out all of the questionnaires. Your other clinical visits during radiation/chemotherapy will be standard of care.

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

Side effects of the study drug and procedures may be mild, or they may severe enough to be life threatening. They may resolve (stop) after you stop the study drug or procedure, or they may continue.

It is possible that BMX-001 would make chemotherapy or radiation not work as well. This might increase your risk that the cancer will not go away, or would come back. It is possible that BMX-001 could make the side effects of chemotherapy and/or

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radiation therapy more severe.

BMX-001 may cause some, all or none of the side effects listed below:

The most common side effects (expected to occur in more than 30% of subjects) are:

- Reaction at the injection site which may include:
- Irritation
- Edema (swelling)
- Itching
- Urticaria (hives)
- Redness and/or red to brown discoloration (discoloration is due to the color of BMX-001 and is not considered to be a side effect)

This kind of reaction is expected to be mild and to resolve within a couple of hours of injection. This reaction responds to treatment with antihistamines.

Less common side effects (expected to occur in 10-30% of subjects) are:

- Dysgeusia (changes to your taste)
- Transient Sinus Tachycardia

Rare side effects (expected to occur in less than 10% of subjects) are:

- Transient hypotension (low blood pressure that lasts for a short time
- Prolongation of the QTc interval after the loading dose. This is a condition in which your heart muscle takes slightly longer than normal to recharge between beats. This can be seen on an ECG and is called a prolonged QT interval. We will monitor this by performing ECGs before and after study drug administration the first day you receive the drug and then twice (or more if indicated by your doctor) during BMX-001 treatment. Many drugs are known to cause this. For more information about this please discuss with your study team.

The following side effects have been observed in less than 1-2% of patients in other BMX-001 trials and for which relation to BMX-001 cannot be ruled out:

- Headache
- Changes in bloodwork affecting white blood cells, liver enzymes and blood potassium levels
- Allergic reaction
- Encephalitis (inflammation of the active tissues of the brain caused by an infection or an autoimmune response)
- Aspiration (this happens when food, liquid, or other material enters a person's

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airway and eventually the lungs by accident)
- Loss of blood flow to part of the brain, which can damage brain tissue
- Blocking of an artery
- Acute Kidney Injury

After discharge, you should be alert for potential symptoms of low blood pressure, which may include dizziness, fainting, lightheadedness, blurry vision, weakness, nausea, vomiting. These symptoms may occur when you change from lying down or sitting to a standing position. If they occur, you should lie down, elevate your feet and contact your health care provider if these symptoms persist.

Blood Draws: The collecting of blood samples to monitor your health throughout this study may cause mild discomfort or pain from the needle puncture and possible bruising or mild bleeding. The risk of infection is slight and will be further reduced by keeping the puncture site clean and dry.

MRI: involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the study. During the study, you can have voice contact and physical contact with someone in attendance if you desire. You may be given a dye intravenously (through a vein) in order enhance the MRI image.

Colonoscopy: A colonoscopy poses few risks. Rarely, complications of a colonoscopy may include: Adverse reaction to the sedative used during the exam and/or Bleeding from the site where a tissue sample (biopsy) was taken or a polyp or other abnormal tissue was removed and/or A tear in the colon or rectum wall (perforation)

Anoscopy: Risks may include: Discomfort post examination, Tearing of the perianal skin or mucosa, Abrasion or tearing of hemorrhoidal tissue. Infection post procedure is possible, but very rarely occurs.

Drug and Food Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical food and drugs, herbal products, over-the-counter (OTC) drugs, vitamins and natural remedies that you are taking before you start the study and before taking any of these products while you are on the study.

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Quality of Life Studies: We want to know your view of how your life has been affected by cancer and its treatment. These Quality-of-life questionnaires looks at how you are feeling physically and emotionally during your cancer treatment. They also looks at how you are able to carry out your day-to-day activities. If any questions make you feel uncomfortable, you may skip those questions and not give an answer.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

For Those of Reproductive Potential:

Female:
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 method(s) 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 3 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 12 months after. Should you become pregnant while on this

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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?
The potential benefits may include protection against dermatitis caused by RT. Additionally, a potential benefit may include protection against development of thrombocytopenia caused by treatment with chemotherapy.

Taking part in this study may or may not make your health better. While researchers hope that BMX-001 protect normal tissues treated during radiation therapy and chemotherapy, since the drug is experimental, it cannot be guaranteed that you will receive any benefit as a result of participating in this research.

What are the possible benefits to other people?
Information obtained from this study may help other patients by contributing to the knowledge of the anal cancer and treatment side effects, and whether this treatment offers potential advantages over other treatments currently available.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to participate and receive standard chemotherapy and radiation therapy without BMX-001.

What will being in this research study cost you?
There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care that you would have received whether or not you were in this study)including the chemotherapy and radiation therapy you will receive will be charged to you or your insurance.

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.

BMX-001 is provided free of charge by BioMimetix, JV LLC while you are on study.

The following research-related costs will not be charged to your insurance:

1. BMX-001 and its administration.
2. Blood draw for pharmacokinetic sampling.

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3. Blood test for clotting studies (PT/PTT)
4. ECG

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 grant funds from The Otis Glebe Medical Research Foundation at The University of Nebraska Medical Center.

The sponsor of the research BioMimetix, JV,LLC is providing BMX-001.

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 or BioMimetix have 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?

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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 for Human Research Protections (OHRP)
    - The Food and Drug Administration (FDA)
- The HIPAA Privacy Rule requires the following groups to protect your PHI:
    - Your health insurance company
    - The Fred and Pamela Buffett Cancer Center Scientific Review Committee (SRC)

Your PHI may also be shared with the following groups. However, these organizations do not have the same obligation to protect your PHI:

- BioMimetix, JV,LLC, which sponsors this research and provides funds the Institution to conduct this research
- Data and Safety Monitoring Committee (DSMC)
- Advarra electronic data capture

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

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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:
Dr. Chi Lin, MD Department of Radiation Oncology
986861 Nebraska Medical Center
Omaha, NE 68198-6861

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 any of the research staff. 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 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 are found to have disease progression, unacceptable side effects ,or if your study doctor determines that it is no longer in your best interest to continue. The sponsor may stop this study at any time. A reason why this may occur includes identification of an unexpected problem with the study drug. If this occurs, you will be notified and your study doctor will discuss this with you.

Will you be given any important information during the study?
You will be informed promptly if the research team gets any new information during

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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 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

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 _____

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

Secondary
Grem, Jean
phone: 402-559-3233
alt #: 402-888-0651
degree: MD

Klute, Kelsey
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alt #: 402-559-1880
degree: MD

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

* Enke, Charles
phone: 402-552-3844
alt #: 402-552-3844
degree: M.D.#21448

* Wahl, Andrew
phone: 402-552-3844
alt #: 402-559-3844
degree: M.D. #24602

* Zhang, Chi
alt #: 402-552-3147
degree: MD

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

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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.