PRINCIPAL INVESTIGATOR: Kevin Camphausen, M.D.

STUDY TITLE: A Phase I Clinical Trial of Selinexor (KPT-330) in Combination with Temozolomide and Radiation Therapy in Patients with Newly Diagnosed Glioblastoma

STUDY SITE: NIH CLINICAL CENTER

Cohort: Affected Patients

Consent Version: 02/13/2023

WHO DO YOU CONTACT ABOUT THIS STUDY?

Kevin Camphausen, M.D. at 301-496-5457 or camphauk@mail.nih.gov

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you make a decision can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being asked to take part in this study because you have brain cancer that has not been treated previously with chemotherapy or radiation therapy.

The purpose of this study is to learn about the highest dose of the study drug selinexor that people can safely tolerate when given in combination with temozolomide and radiation therapy.

The use of selinexor in this study is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat brain cancer. Radiation therapy and the other drug called temozolomide have been approved for the standard treatment for this disease. However, the FDA has given us permission to use both drugs (selinexor and temozolomide) in combination with radiation for this study.

There are other drugs/therapy that may be used to treat your disease, and these can be given by your regular cancer doctor if you are not in this study. As per standard of care for brain cancer, radiotherapy and temozolomide can be given by your regular cancer doctor. The way in which treatment is given in this study and the side effects could be different than if you were to receive standard care. The most common side effects of radiation therapy for brain cancer are fatigue and headache, which may be treated with standard medications. The most frequently occurring side effects of temozolomide are nausea, vomiting, and constipation. The most

frequently occurring side effects of selinexor are nausea, decreased appetite, vomiting, decrease in blood cell counts, constipation, diarrhea and weight loss. Selinexor treatment could add the risk of missing or delaying temozolomide and radiation treatment (due to some overlapping side effects) which you could be getting if you are not participating in this study.

Risks are explained in detail later in consent. Some risks are unknown. Specifically, the risks that may occur from receiving the combination of the study drugs and radiation are unknown. It is possible that some of the potential side effects of the combination of these treatments may be the same as each given alone. Please talk to your doctor if have any questions regarding risks or alternative treatments.

If you decide to join this study, here are some of the most important things that you should know that will happen:

On your first day before stating the study treatment, we will do physical and neurological examinations and a pregnancy test. You will not be allowed to participate in the study if you are pregnant. You will have an MRI and CT scan of the brain if you have not had one in 3 weeks. You will complete some survey forms which would help us to assess your well-being.

Radiation therapy is usually given once a day, Monday through Friday, except for holidays. You will receive radiation for up to six weeks to the area in your brain where your tumor is. These will be outpatient visits and each one will last about an hour.

Selinexor will be taken by mouth once or twice a week. In the first group of patients, selinexor will be given once a week in weeks 1, 2, 4, and 5. If this first group tolerates the starting dose, the dose and/or frequency will be increased for the next sets of patients. Your dose will depend on when you enter the study. Please ask your doctor what dose you will be getting and how often you will get it.

Temozolomide will begin on the first day of radiation and be taken by mouth once a day. temozolomide will continue until the completion of radiation. Temozolomide may be continued as part of standard of care by your home oncologist or under this study.

Once your radiation treatment is completed, you will return to the Radiation Oncology Clinic for a follow-up visit at one month after the completion of therapy, followed by at least every 2-month intervals for the first 2 year(s), and then at least every 3 months thereafter for another year for a total of 3 years.

You are free to stop participating in the trial at any time. If you decide to stop, the study doctor may ask you to agree to certain tests to make sure it is safe for you to stop.

The remaining document will now describe more about the research study. This information should be considered before you make your choice. Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The

term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

This is a research study. The purpose of this research study is to learn about the highest dose of selinexor that people can safely tolerate when given in combination with temozolomide and radiation therapy.

We are asking you to join this research study because you have brain cancer that have not been treated previously with chemotherapy or radiation therapy.

Selinexor is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to treat brain cancer. However, the use of temozolomide in addition to radiation therapy is approved to treat brain cancer.

WHAT WILL HAPPEN DURING THE STUDY?

Before you begin the study, you will have certain tests performed on another protocol to determine whether you are eligible to participate. Once it is determined that you are eligible, you will be asked to sign this consent.

During the study

	Treatment Cycle (6 weeks)						Follow-up visits (total 3 years)		
							After 1 month	Every 2 months for 2 yrs	Every 3 months for 3rd yr
Procedure	**Wk 1**	**Wk 2**	**Wk 3**	**Wk 4**	**Wk 5**	**Wk 6**			
Outpatient visit	X	X	X	X	X	X	X	X	X
Physical and neurological examination	X						X	X	X
Vital signs and weight	X	X	X	X	X	X	X	X	X
Routine blood tests	X	X	X	X	X	X	X	X	X
Pregnancy Test	X								
Urine test	X								
Radiation	Every day up to six weeks (M-F)								
Selinexor[#]	X	X	X	X	X	X			
TMZ*	X	X	X	X	X	X			
Brain MRI	X						X	X	X
CT scan	X								
Questionnaires	X						X	X	X

[#]Selinexor will be taken by mouth as often as twice a week depending on when you enrolled in the study. Please ask your doctor what dose you will be getting based on when you enter in the study.

* Temozolomide will begin on the first day of radiation and be taken by mouth once a day. Temozolomide will continue until the completion of radiation.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for 3 years.

Once your radiation treatment is completed, you will return to the Radiation Oncology Clinic for follow-up visits after your radiation treatment at one month after the completion of therapy, followed by at least every 2-month intervals for the first 2 year(s), and then at least every 3 months thereafter for a total of 3 years. At these times you will have blood tests, a physical and neurological examination and an MRI of the brain. You will need to complete some survey forms to see how you are doing. Some of these visits may be done remotely by phone, video phone, email or any other NIH approved method.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 24 people participate in this study at the NIH Clinical Center.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

This study involves some risks from the study drugs, radiation and some of the procedures. The risks that may occur from receiving the combination of the study drugs and radiation are unknown. It is possible that some of the potential side effects of the combination of these treatments may be the same as each given alone. The known risk for the study are described below.

Risks of selinexor

Very common side effects (≥10%):

In 100 people receiving selinexor more than 10 people may have:

- Nausea
- Vomiting
- Diarrhea
- Weight loss
- Constipation
- Fatigue and asthenia – loss of energy; weakness
- Decreased appetite
- Dehydration
- Abdominal pain
- Dysgeusia – change in taste
- Shortness of breath
- Cough
- Dizziness
- Fever
- Blurred vision
- Headache
- Difficulty falling asleep
- Low platelets in the blood (thrombocytopenia), which may increase the risk of bleeding
- Decrease in red blood cells (anemia) causing fatigue
- Decrease in white blood cells (leukopenia), which may increase the risk of infection
- Decrease in neutrophils (a type of white blood cell that helps fight infections)
- Pneumonia
- Low blood sodium which may increase the risk of seizures
- Low potassium which may cause weakness, muscle cramps and spasms
- Peripheral edema – swelling in extremities due to accumulation of fluid, usually in legs
- High blood sugar which may cause fatigue, increased thirst/hunger, frequent urination, weight loss, numbness and tingling in hands/feet

Common side effects (≥1-10%)

In 100 people receiving selinexor about 1 to 10 people may have:

- Rash
- Eye disorders including cataract (new or worsened), dry eye, visual impairment, seeing flashes of light
- Night sweats
- Dry mouth
- Stomatitis – a condition that causes painful swelling and sores inside the mouth
- Dyspepsia – indigestion
- Chills
- Hypotension – low blood pressure
- Hypertension
- Tachycardia – fast heart rate
- Nosebleed
- Contusion (bruise due to body injuries such as fall)
- Electrolyte disturbances including:
- Low phosphate which may cause muscle weakness and fatigue
- Low magnesium which may cause muscle twitches and cramps
- Low calcium which may cause numbness and tingling in hands/feet/face, muscle stiffness and cramps
- High potassium which may cause muscle weakness, palpitations or irregular heartbeats and chest pain
- Low albumin (which may cause swelling especially of the hands/feet, weakness or exhaustion)
- Peripheral neuropathy – weakness, numbness, and pain from nerve damage, usually in the hands and feet
- Decrease in lymphocytes – a specific type of white blood cell that are part of your immune system
- Increase of creatinine in the blood due to a reduction in kidney function, often related to dehydration
- Elevated liver enzymes including alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased
- Elevated pancreatic enzymes including high amylase and high lipase
- Muscle weakness
- Febrile neutropenia – fever in the absence of a normal white blood cell response that may mean you have an infection
- Urinary tract infection
- Sepsis (including septic shock)- potentially life-threatening complication of an infection
- Pain in joints and muscles
- Malaise (a general feeling of being ill or bodily weakness)
- Muscle spasms
- Gait disturbance

- Hair loss
- Itching
- Depression
- Syncope - fainting
- Cognitive disorder
- Mental status changes including confusion

Rare side effects (>0.1-1%)

In 1000 people receiving selinexor about 1 to 10 people may have:

- Tumor lysis syndrome – potentially a life-threatening side effect caused by the rapid breakdown of tumor cells and may cause irregular heartbeat, kidney failure or abnormal blood test results which included elevated uric acid level, elevated serum potassium and phosphorus levels, and a decreased calcium level.
- Gastroenteritis (stomach flu)

Rare side effects (>0.01-0.1%):

In 10,000 people receiving selinexor about 1 to 10 people may have:

- Acute cerebellar syndrome – symptoms can include a sudden loss of coordination, balance or slurred speech

Serious adverse effects (≥3 cases reported as related to selinexor by the principal investigator):

- Cardiac failure
- General physical health deterioration
- Multiple organ dysfunction syndrome
- Lung infection
- Bacteremia – bacterial infection in the blood
- Bronchitis – infection of tubes that carry air to and from lungs
- Decreased ejection fraction – reduction in amount of blood pumped out of heart
- Encephalopathy – brain disease, damage, or malfunction, which can present different symptoms that range from mild, such as some memory loss or subtle personality changes, to severe, such as dementia, seizures, or coma
- Delirium – state of acute confusion
- Acute kidney injury
- Pulmonary embolism– pulmonary embolism occurs when a clump of material, most often a blood clot, gets wedged into an artery in your lungs
- Hypoxia – an absence of oxygen supply at tissue level

Risks of temozolomide

COMMON, SOME MAY BE SERIOUS In 100 people receiving temozolomide, more than 20 and up to 100 may have:
• Constipation, nausea, vomiting, diarrhea • Dizziness • Muscle weakness, paralysis, difficulty walking • Trouble with memory • Tiredness • Difficulty sleeping • Hair loss
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving temozolomide, from 4 to 20 may have:
• Headache, seizure • Infection, especially when white blood cell count is low • Low blood count which may cause tiredness • Bruising, bleeding
RARE, AND SERIOUS In 100 people receiving temozolomide, 3 or fewer may have:
• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Cancer of bone marrow caused by chemotherapy • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require blood transfusions • Rash • Severe skin rash with blisters and can involve inside of mouth and other parts of the body

Risks from Scans

Radiological testing, such as CT scans, MRIs, and radioactive tracer may be used to assess the treatment of your disease at various times during therapy. The cumulative radiation exposure from these tests is considered very small and is unlikely to adversely affect you or your disease. Because some of these tests require administration of contrast you could experience pain, bruising, and/or infection at the site of injection, or an allergic reaction to the contrast agent. Please notify the investigator if you know or suspect you are allergic to contrast dye.

Risks from MRI

People are at risk for injury from the MRI magnet if they have some kinds of metal in their body. It may be unsafe for you to have an MRI scan if you have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metal prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, tattoos, an implanted delivery pump, or shrapnel fragments. Welders and metal workers may have small metal fragments in the eye. You will be screened for these conditions before having any MRI scan. If you have a question about metal in

your body, you should inform the staff. You will be asked to complete an MRI screening form before each MRI scan you have.

In addition, all magnetic objects (like watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away.

There are no known long-term risks of MRI scans.

Risks from MRI contrast

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive gadolinium if you previously had an allergic reaction to it. You will be asked about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis (NSF)". This condition always involves the skin and can also involve the muscles, joints and internal organs. NSF has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is below the safe level.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA has issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The long-term effects of the retained gadolinium are unknown. Some types of gadolinium contrast drugs are less likely to remain in the body than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain in the body. We will also give you additional information called a "Medication Guide." Upon request, we will give you individual information about retained gadolinium we see on your studies.

Risks from Radiation

Overall radiation risks

During a year in this research study, your tumor will be exposed to 60 Gy of radiation divided in 30 treatment sessions. You will also receive a much smaller amount of radiation from a CT scan used to plan your treatment. The amount of radiation from this scan adds minimal additional risk to the higher radiation doses received in the course of treatment.

Risks from radiation therapy

DURING OR SHORTLY AFTER TREATMENT COURSE	AFTER TREATMENT COURSE (MONTHS TO YEARS)
COMMON	**COMMON**
Skin redness and irritation in area treated	Scalp discoloration and thickening
Hair loss in area treated, including eyebrows	Mild decrease in memory or ability to think
Tiredness	Permanent thinning or loss of hair in treated area including eyebrows
Worsening of neurologic symptoms present prior to radiation	
UNCOMMON	**UNCOMMON**
Tiredness, headache, weakness, numbness, or other neurologic deficit which may require steroid treatment	Permanent loss (death) of brain cells
	Development of seizures
	Severe memory loss
Nausea, vomiting, weight loss	Cataracts in eyes
Increase in seizure activity if already present	Hearing loss
Dry eyes	Dry eyes
RARE	**RARE**
Decreased blood cell count	Death of brain cells causing swelling in the brain and requiring long term steroid treatment, hospitalization, or/or surgery
Excessive need of sleep	
OTHER	Loss or decrease of vision
	Change in hormone levels from the pituitary
	EXTREMELY RARE
	Development of new tumors in scalp, skull or brain
	Difficulty with control of water balance, thirst, loss of salts from body
	Loss of function specific to the area affected such as: vision, sensation, memory, judgement, motor skills
	Damage to retina causing blindness
	Damage to blood vessels leading to stroke or may be fatal.

Other risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions. A little more than 2 tablespoon of blood will be drawn during screening and/or baseline and a little less than 1 tablespoon will be drawn during each follow-up.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaire, please contact your doctor or the study nurse.

Overlapping side effects due to selinexor may cause you to miss or delay temozolomide and radiation treatment which is a standard therapy with demonstrated clinical benefit for your cancer.

What are the risks related to pregnancy?

If you are capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You will need to practice an effective form of birth control before starting study treatment, during study treatment, and for one month after you finish study treatment (the restricted period). If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to a fetus. You must tell the study doctor if your birth control method fails during the restricted period. If you think or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible.

You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before exposing you to radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

If you are a sexually active person with a partner capable of becoming pregnant, it is important that your partner not become pregnant during the restricted period. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become pregnant during the restricted period, please contact the research team member identified at the top of this document as soon as possible. If you and your partner plan for your partner to become pregnant after the restricted period, please discuss this with the study team.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study.

However, the potential benefit to you might be shrinking of your tumor or a decrease in your symptoms that are caused by the cancer. Because there is not much information about the drug's effect on your cancer, we do not know if you will benefit from taking part in this study.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study because what we learn in this study may eventually be used to treat others with your disease.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could

- choose to be treated with radiation or standard drugs already approved by the FDA for your disease
- choose to take part in a different study, if one is available
- choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

You should discuss with your doctor your other choices and their risks and benefits.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

We are not planning to return any research findings.

EARLY WITHDRAWAL FROM THE STUDY

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease worsens or comes back during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if you become pregnant
- if selinexor may become unavailable
- if new information shows that another treatment would be better for you
- if you do not follow the study rules
- if the study is stopped for any reason

In this case, you will be informed of the reason therapy is being stopped.

After therapy is stopped we would like to see you for a safety visit 30 days after your last dose.

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to KaryoPharm Therapeutics Inc. or designated representatives.

WILL YOUR SPECIMENS OR DATA BE SAVED FOR USE IN OTHER RESEARCH STUDIES?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding cancer, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research

or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. These researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

How Long Will Your Data be Stored by the NIH?

Your data may be stored by the NIH indefinitely.

Risks of Storage and Sharing of Data

When we store your data, we take precautions to protect your information from others that should not have access to it. When we share your data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your data.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

Will you receive reimbursement or direct payment by NIH as part of my participation?

On this study, the NCI will cover the cost for some of your expenses. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy. You will be given a summary of the policy which provides more information.

Will taking part in this research study cost me anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

- If some tests and procedures are performed outside the NIH Clinical Center, you may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the NIH Clinical Center.
- Once you have completed taking part in the study, medical care will no longer be provided by the NIH Clinical Center.

CONFLICT OF INTEREST(COI)

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

KaryoPharm Therapeutics Inc is providing selinexor for this study to NIH without charge. No NIH employee involved in this study receives any payment or other benefits from KaryoPharm Therapeutics Inc.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor, Center for Cancer Research (CCR)
- Qualified representatives from KaryoPharm Therapeutics Inc., the pharmaceutical company who produces selinexor.

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical records we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your medical record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Kevin Camphausen, MD at 301-496-5457 or camphauk@mail.nih.gov. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral should sign below if either:

1. **A short- form consent process only: has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Signature of Witness	Print Name of Witness	Date

NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.