LS1981 / 19-009349

# Phase Ib Trial of Low-Dose Selinexor (KPT-330) in Combination With Choline Salicylate (CS) for the Treatment of Patients With Non-Hodgkin Lymphoma (NHL), Hodgkin Lymphoma, Histiocytic/Dendritic Cell Neoplasms, or Multiple Myeloma

NCT04640779

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MAYO CLINIC

Name and Clinic Number

**Approval Date:** **September 18, 2025**
**Not to be used after:** **September 17, 2026**

# RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

**Study Title:** LS1981, Phase Ib trial of Low-Dose Selinexor (KPT-330) in Combination with Choline salicylate (CS) for the Treatment of Patients with Non-Hodgkin Lymphoma (NHL), Hodgkin Lymphoma, Histiocytic/Dendritic Cell Neoplasms or Multiple Myeloma

**IRB#:** 19-009349

**Principal Investigator:** Jonas Paludo, MD and Colleagues

## Key Study Information

| This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered. | |
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| **It's Your Choice** | This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part. |
| **Research Purpose** | The purpose of this research is to learn about the combination of choline salicylate and selinexor for patients with non-Hodgkin or Hodgkin lymphoma, histiocytic/dendritic neoplasm, or multiple myeloma whose prior treatment did not help their cancer. We want to find out more about the side effects of the combination, what doses are safe for patients, and to collect information on how your cancer responds to the drug combination.<br>The selinexor and choline salicylate drug combination is investigational and is not approved by the Food and Drug Administration (FDA) to use as treatment in this type of cancer. However, selinexor is approved for treatment in multiple myeloma and choline salicylate is approved as a mild pain reliever. |

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| **What's Involved** | To see if you can be in the study, you will need to have some screening tests and procedures. If you have already had some of these done at a recent doctor's office visit, then the tests may not need to be done again.<br><br>If you are a person of childbearing potential, a pregnancy test will be done before you start treatment.<br><br>If you qualify for the study, you will receive selinexor twice per week and choline salicylate daily. Both drugs are taken by mouth (oral). Since we are evaluating different doses of the combination, the dose will be decided when you enter the study.<br><br>You will receive treatment for about 6 months. Then if your cancer is staying the same or getting better, you may be able to receive the treatment for another 6 months. During the treatment, you will return to Mayo Clinic every 28 days for treatment except for the first 2 months. During those months, you will need to be at Mayo Clinic for 8 days for some required research blood tests. Then after that, there will be up to 11 more monthly visits.<br><br>During these visits, your participation also includes physical exams; review of your side effects; routine blood tests; scans to follow your tumor size; mandatory research blood tests and research tissue collections from a previous biopsy. Both males and females will need to use a highly effective form of birth control during study and for 3 months after the last study dose.<br><br>These visits are similar to what you would have even if you aren't on the study. |
| **Key Information** | There are risks to the study drugs that are described later in this document. Some of the very common side effects of selinexor are fatigue, weight loss, nausea, low platelet count, low hemoglobin count, infections, decreased appetite, vomiting, diarrhea, and low sodium count. Some of the common side effects of choline salicylate are constipation, diarrhea, upper abdomen pain, heartburn, nausea, and vomiting. |

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| | Many side effects go away shortly after the treatment is stopped, but in some cases side effects can be serious, long-lasting problems, or may never go away. There may be side effects that are unknown. It is important to review the risk section carefully.<br><br>The costs related to this research such as the choline salicylate and selinexor medications, research blood and tissue collections will be paid for by the research study. However, you or your insurance company will need to pay for the tests, procedures, and any other medications that are a part of standard of care. If you get injured because of study participation, we will help you get treatment; however, the costs for this care will be billed to you or your insurance.<br><br>We do not know whether this drug combination will make your cancer better or not. What we learn from this study will help doctors know more about selinexor and choline salicylate as a treatment for these cancers.<br><br>You do not need to be in this study to receive treatment for your cancer. Your doctor will discuss what your options are. |
| **Learn More** | If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us. |

## Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

## Contact Information

| If you have questions about … | You can contact … |
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| ▪ Study tests and procedures<br>▪ Materials you receive<br>▪ Research-related appointments<br>▪ Research-related concern or complaint<br>▪ Research-related injuries or emergencies<br>▪ Withdrawing from the research study | **Principal Investigator:**<br>Jonas Paludo, M.D.<br>**Phone:** (507) 266-4994<br><br>**Institution Name and Address:**<br>Mayo Clinic<br>200 First St SW<br>Rochester, MN 55905 |
| ▪ Rights of a research participant | **Mayo Clinic Institutional Review Board (IRB)**<br>**Phone:** (507) 266-4000<br>**Toll-Free:** (866) 273-4681 |
| ▪ Rights of a research participant<br>▪ Any research-related concern or complaint<br>▪ Use of your Protected Health Information<br>▪ Stopping your authorization to use your Protected Health Information<br>▪ Withdrawing from the research study | **Research Participant Advocate (RPA)**<br>**(The RPA is independent of the Study Team)**<br>**Phone:** (507) 266-9372<br>**Toll-Free:** (866) 273-4681<br><br>**E-mail:**<br>researchparticipantadvocate@mayo.edu |
| ▪ Billing or insurance related to this research study | **Patient Account Services**<br>**Toll-Free:** (844) 217-9591 |

**Other Information:**

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.

A description of this research study will be available on MayoClinic.org. This website will not include information that can identify you. You can search this website at any time.

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## Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have non-Hodgkin or Hodgkin lymphoma, histiocytic/dendritic cell neoplasm, or multiple myeloma and the previous treatment you received is not effective against your cancer.

This study is being conducted at Mayo Clinic only. The plan is to have up to 39 people take part in this study at Mayo Clinic.

## Why is this research study being done?

We are doing this research study to learn about the combination of choline salicylate and selinexor. We want to find out more about the side effects of the combination, what doses are safe for patients, and to collect information on how your cancer responds to the drug combination. The doses of both drugs you receive will depend on when you are enrolled on to the study.

The drug combination of selinexor and choline salicylate is experimental and isn't approved by the U.S. Food and Drug Administration (FDA). Selinexor is FDA approved when given with dexamethasone for previously treated relapsed multiple myeloma and when given alone for relapsed DLBCL. Selinexor is currently being studied in other types of cancer. Choline salicylate has been used as a mild pain reliever, but has not been used in the treatment of cancer. The combination is investigational because the two drugs have never been given together. However, the FDA has allowed the use of this drug combination in this research study.

## Information you should know

**Who is Funding the Study?**
Karyopharm Therapeutics is providing the selinexor for the study. Karyopharm Therapeutics will pay the institution to cover costs related to running the study. The Lymphoma SPORE will purchase the choline salicylate for use in this study. Eastern Cooperative Oncology Group (ECOG) will provide funding for a portion of the research blood tests.

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**Information Regarding Conflict of Interest:**
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

## How long will you be in this research study?

You will receive treatment for about 6 months. At that time, if your disease is the same or better, you and your doctor will decide if you should continue on treatment for another 6 months. When you complete treatment, if your disease has gotten worse, or if you have too many side effects from treatment, you will go off study.

## What will happen to you while you are in this research study?

If you agree to be in this study, you will receive up to 12 cycles of treatment with selinexor and choline salicylate. A treatment cycle lasts for 28 days.

All patients will receive selinexor two times a week. Choline salicylate is taken on Days 1-28 every cycle. Both medications are taken by mouth (orally). The dose of selinexor and choline salicylate will be different depending on when you enroll in the study. The first group of 3 patients will start with low doses. If no bad side effects occur, another 3 patients will be enrolled and started on a higher dose.
This will continue until unacceptable side effects occur or the maximum planned dose is reached. Once the maximum dose is reached, another 3 patients will be treated to make sure this is the safest dose.

During the Screening visit, we will do some tests and procedures to see if you are eligible to take part in the research study. Your doctor will review the results of these tests and procedures. If you are not eligible, your doctor will tell you why. At this visit, we will:

- Ask you about your medical history
- Give you a physical exam, including height and weight
- Ask you about your activity level and symptoms

- Draw routine blood tests to check your hematology and chemistry blood counts, thyroid function test, LDH, Human Immunodeficiency Virus (HIV) screen, and Hepatitis B and C screen
- Draw a pregnancy test, if you are a person of childbearing potential
- Perform an electrocardiogram (EKG) to look at your heart rhythm
- Perform a PET/CT scan to record your tumor size (for lymphoma and histiocytic/dendritic cell neoplasms)
- Take a photograph of skin lesions, if needed, to record tumor size (for lymphoma and histiocytic/dendritic cell neoplasms)
- Disease assessments for multiple myeloma includes:
    - blood and urine tests
    - bone survey, whole body low dose CT scan, whole body MRI, or PET/CT
    - bone marrow aspirate and biopsy (including FISH and Minimal Residual Disease (MRD))

If you have already had some of these tests and procedures as part of regular cancer care, it may not be necessary for them to be done again. Your doctor will let you know.

If the HIV or hepatitis test results are positive, it is the state law that they be reported to the State Department of Health. If your test returns positive, the researcher will tell you how to find medical help and counseling, as needed. The test results will also be put in your medical record. You may need further testing and you may not be able to take part in the study. Your health insurer or you will have to pay for the cost of the repeat test, any follow-up medical care, or counseling.

If you are eligible for the study, the following will be done for research purposes only to help us better understand how the drugs work together:

- Mandatory research blood tests called pharmacokinetics (PK) (about 8 teaspoons (42 mls) total) will be collected on the first three patients at each dose level. Your doctor will let you know if you will have the PKs collected.
- Mandatory research blood tests (about 4 tablespoons (56 mls) total) will be collected to store for future research.
- Mandatory tumor tissue sample from a previous biopsy (for patients with lymphoma, extramedullary myeloma or histiocytic/dendritic cell neoplasms).
- Optional research tissue collections for future research (for patients with lymphoma, extramedullary myeloma or histiocytic/dendritic cell neoplasms):
    - If you have a biopsy for clinical reasons at any time during the study, we will ask to keep the left-over tissue.
    - If you have a biopsy for clinical reasons at any time before you start the study or during the study, we will ask to collect an additional research tissue sample.

- Prior to Cycle 3, we will ask you to have a CT or Ultrasound guided biopsy to collect research tissue samples. For this biopsy, x-rays are used to guide the needle placement during the biopsy procedure.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

Day 1 of the treatment will be given in the outpatient treatment area on Gonda 10. You will receive a supply of the selinexor and choline salicylate to take home with you for the rest of the days in a cycle. The selinexor may be taken with or without food. The choline salicylate can be mixed with 4-8 ounces (½ cup - 1 cup) of liquids except for milk, drinks with added calcium, or alcoholic beverages, to make it taste better, if needed. Choline salicylate should not be mixed with anti-acids. Choline salicylate should be taken about 30 minutes before meals. You will be asked to fill out a medication diary each day to document when you took the oral medications. Your doctor will discuss this with you.

If you are one of the first 3 patients in a dose level, you will have research bloods (PKs) collected during Cycle 1 on Days 1-3 and 15-17. You should plan on being at Mayo Clinic for 3 days for each of these visits. Your doctor will discuss this with you.

During Cycles 1 and 2:

- Day 1
  - Have a physical exam including weight
  - Ask you about your activity level and symptoms
  - Draw routine blood tests to check your hematology and chemistry blood counts, and LDH
  - Take pre-medications within 1 hour prior to the selinexor
  - Cycle 1: Have a research blood test collected prior to selinexor (for PKs, about ½ teaspoon (3 mls), if applicable); and for future research, about 2 tablespoons (28 mls)
  - Cycle 1 only: Take the selinexor by mouth (orally) as instructed. Choline salicylate will not start until Day 3.
  - Prior to Cycle 2: Have blood and urine tests to monitor your disease status (for multiple myeloma only)
  - Cycle 2: Take the selinexor as instructed. Take choline salicylate daily by mouth (orally) as instructed.

- Cycle 1: Have research blood tests (PKs) collected at 1, 2, 4, and 6-8 hrs. after taking the study medication(s) (about ½ teaspoon (3 mls) each time), if applicable.
- Cycle 2: Bring any unused study medications and your completed diary to your doctor's appointment.

- Day 2
  - Cycle 1: Have a research blood test (PK) collected about 24 hours after Day 1 study medication(s) (about ½ teaspoon (3 mls), if applicable
  - Cycle 1: Do not take choline salicylate
  - Cycle 2: Take choline salicylate by mouth daily as instructed until Day 28

- Day 3
  - Take pre-medications 1 hour before selinexor as instructed
  - Cycle 1: Have a research blood test (PK) collected about 48 hours after Day 1 study medication(s) (about ½ teaspoon (3 mls)), if applicable
  - Cycle 1: After the research blood draw, take selinexor by mouth as instructed and start taking choline salicylate by mouth daily as instructed until Day 28 (for 26 days)

- Days 8 and 10
  - Take pre-medications 1 hour before selinexor as instructed
  - Take selinexor by mouth one time each day as instructed
  - On Day 8, have routine blood tests drawn to check your hematology and chemistry blood counts

- Day 15
  - Take pre-medications 1 hour before selinexor as instructed
  - Take selinexor and choline salicylate by mouth as instructed
  - Cycle 1: Have research blood tests (PKs) collected at 1, 2, 4, and 6-8 hrs. after taking the selinexor and choline salicylate (about ½ teaspoon (3 mls) each time), if applicable

- Day 16
  - Cycle 1: Have a research blood test (PK) collected about 24 hours after taking selinexor and choline salicylate Day 15 doses (about ½ teaspoon (3 mls)), if applicable
  - Take choline salicylate dose as instructed

- Day 17
  - Take pre-meds 1 hour before selinexor as instructed
  - Cycle 1: Have a research blood test (PK) collected about 48 hours after taking selinexor and choline salicylate Day 15 doses (about ½ teaspoon (3 mls)), if applicable
  - Take selinexor as instructed
  - Take choline salicylate dose as instructed

- Days 17, 22, and 24
  - Take pre-medications 1 hour before selinexor as instructed
  - Take selinexor and choline salicylate by mouth as instructed
  - On Day 22, have routine blood tests drawn to check your hematology and chemistry blood counts

- Days 19-28
  - Take choline salicylate dose as instructed

During Cycles 3-12:

- Day 1
  - Have a physical exam including weight
  - Ask you about your activity level and symptoms
  - Draw routine blood tests to check your hematology and chemistry blood counts, and LDH
  - Bring any unused study medications and your completed diary to your appointment with your doctor.
  - Have a PET/CT scan to record your tumor size after Cycles 3, 6, 9 and 12) (for lymphoma and histiocytic/dendritic cell neoplasms)
  - Have a photograph of skin lesions, if needed, to record tumor size after Cycles 3, 6, 9 and 12) (for lymphoma and histiocytic/dendritic cell neoplasms)
  - Have blood and urine tests to monitor your disease status. Once your disease responds, then it will be assessed every other cycle and as needed. (for multiple myeloma only)
  - Have a bone marrow biopsy and aspirate performed including FISH & MRD, if your cancer is responding (for multiple myeloma only)
  - Take pre-medications within 1 hour prior to the selinexor
  - Cycle 3 only: Have a research blood test collected for future research (about 2 tablespoons (28 mls)
  - Cycle 3 only: Have an Ultrasound (US) or CT guided research tumor biopsy, if you agree to this (for lymphoma, extramedullary myeloma, and histiocytic/dendritic cell neoplasms)
  - Take the selinexor and choline salicylate by mouth (orally) as instructed

- Days 2-28
  - Take choline salicylate by mouth daily as instructed

- Days 3, 8, 10, 15, 17, 22, and 24
  - Take pre-medications within 1 hour prior to the selinexor
  - Take the selinexor by mouth (orally) as instructed

After 6 cycles of treatment, your disease status will be checked. Patients whose cancer has gotten better or stayed the same and who are tolerating the treatment may receive 6 additional cycles, for a total of 12 cycles. You and your doctor will decide if you should continue. For patients whose cancer grew or who had too many side effects, the treatment will be stopped.

At End of Treatment:
- Have a physical exam including weight
- Ask you about your activity level and symptoms
- Draw routine blood tests to check your hematology and chemistry blood counts, and LDH
- Bring any unused study medications and your completed diary to your appointment with your doctor.
- Have a PET/CT scan to record your tumor size (for lymphoma and histiocytic/dendritic cell neoplasms)
- Have a photograph of skin lesions, if needed, to record tumor size (for lymphoma and histiocytic/dendritic cell neoplasms)
- Disease assessments for multiple myeloma includes:
  - blood and urine tests
  - bone survey, whole body low dose CT scan, whole body MRI, or PET/CT
  - bone marrow aspirate and biopsy, if needed

## What are the possible risks or discomforts from being in this research study?

You may have side effects while on study. Many side effects go away shortly after the selinexor and choline salicylate are stopped, but in some cases side effects can be serious, long-lasting problems, or may never go away.

Some side effects may not be known. Side effects may range from mild to life- threatening. As with any medication, allergic reactions are possible. There may also be a risk of death. Other drugs may be given to make side effects less serious and less uncomfortable.

Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

**Risks and side effects of selinexor include:**
**Very common risks of selinexor:** ***these happen in at least 10 out of 100 patients (10% or more)***

- Nausea
- Vomiting
- Decreased appetite (anorexia)
- Weight loss
- Change in taste
- Diarrhea
- Constipation
- Dehydration
- Shortness of breath
- Fever
- Dizziness
- Weakness (asthenia)
- Blurred vision
- Low platelets in the blood (which may increase the risk of bleeding)
- Anemia (which may cause tiredness or may require blood transfusions)
- Decrease in white blood cells (which may increase the risk of infection)
- Low sodium levels (that may increase risk of seizure or may cause cramps and spasms)
- Fatigue
- Abdominal pain

**Less Common Risks of Selinexor :** ***these happen in about 1 to 10 out of 100 patients (1% to less than 10%)***

- Eye disorders (cataract, visual disturbances and dry eye)
- Fever with reduced white blood cell count (may indicated an infection)
- Pneumonia
- Gastroenteritis (inflammation of the stomach and/or intestine)
- Respiratory tract infection
- Urinary tract infection
- Infection of the tubes that carry air to and from the lungs (bronchitis)
- Bacterial infection in the blood (bacteremia)
- Sepsis including septic shock (a potentially life-threatening complication of an infection)
- Fainting
- Mental status changes including confusion

- State of acute confusion (delirium)
- Nose bleed
- Changes in kidney function testing

**Uncommon Risks of Selinexor: these happen in 1 to 10 out of 1,000 patients (less than 0.1% to 1%)**

- Rarely tumor lysis syndrome (potentially a life-threatening condition caused by the rapid breakdown of tumor cells; symptoms may include weakness, dysuria, oliguria, vomiting, cramps, seizures, spasms, altered mental status, weakness and paralysis)

Post marketing risks include plasma cell myeloma and insomnia

**Risks and side effects of choline salicylate include:**
**Likely risks of choline salicylate:** ***these happen in at least 1 out of 100 patients (1% or more)***

- Constipation
- Diarrhea
- Pain or discomfort in upper abdomen (Dyspepsia)
- Pain or discomfort below ribs in upper abdomen (Epigastric pain)
- Painful burning feeling in your chest or throat (Heartburn)
- Nausea
- Vomiting
- Stomach ulcers
- Stomach bleeding
- Noise or ringing in the ears (Tinnitus) or if you already have tinnitus, it might get worse
- Dizziness
- Being more sleepy than usual during the day (Drowsiness)
- Headache
- Lethargy which may cause sleepiness, fatigue, and sluggish
- Hearing loss (Auditory impairment)

**Less likely risks of choline salicylate:** ***these happen in less than 1 out of 100 patients (less than 1%)***

Based on postmarketing and/or case reports:

- Loss of appetite (Anorexia)
- Asthma
- Bruising
- Confusion
- Duodenal ulcer
- Change in sense of taste (Dysgeusia)

- Swelling in hands and feet (Edema)
- Nose bleeds (Epistaxis)
- Skin lesions breaking out (Erythema multiforme)
- Irritation of the esophagus (Esophagitis)
- Development of a hole in the lining of the stomach (Gastric ulcer)
- Perception of something that is not present (Hallucination)
- Hearing loss (irreversible)
- Increased blood urea nitrogen
- Increased liver enzymes
- Increased serum creatinine
- Occult blood in stools
- Itching of the skin (Pruritus)
- Skin rash
- Weight gain

**Serious risks of choline salicylate that have been reported:**

- Salicylate toxicity (salicylism): Symptoms include tinnitus (ringing in the ears), vertigo (loss of balance), nausea, vomiting, and diarrhea

**Other Research Related Risks:**
**Blood Draw Risks**
The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

**Optional CT or Ultrasound Guided tumor biopsy (Prior to Cycle 3):**
The CT or Ultrasound guided tumor biopsy risks include bleeding, infection, the need for additional procedures, or organ damage. All of these risks are very rare, <1 in 100 to 1000.

If the tumor biopsy is done by CT guidance, you will be exposed to radiation from this procedure. The amount of radiation from this has a low risk of harmful effects. If you are a person of childbearing potential and the biopsy is done in the abdominal/pelvic area, you will also need to have a pregnancy test done prior to the procedure.

**Genetic Testing**
This study may involve testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). This testing may include whole genome sequencing (mapping your entire genetic code). You will not be notified of the genetic test results and they will not be put into your medical record.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.

Be aware that this new Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**Pregnancy Risk – Female**
Selinexor can harm an unborn or nursing baby. Therefore, women who are pregnant or nursing a child cannot participate in this study. You will have a pregnancy test prior to going on the study, to make sure you are not pregnant now. You must also not plan to become pregnant during the study.

It is not expected that very many women participating in this study can become pregnant. But if you are a female participant in this study, are sexually active, or have a chance of becoming pregnant, it is important that you use a highly effective birth control method during study treatment and for 3 months after your last dose. In addition, you must agree to refrain from egg donation from first dose until at least 90 days following your last dose of selinexor.

Examples of highly effective birth control methods are:

- Total abstinence, when this is in line with your preferred and usual lifestyle. Periodic abstinence like calendar, ovulation, symptom-thermal, post-ovulation methods, and withdrawal are not acceptable methods of contraception.
- Female sterilization, when you have been already surgically sterilized prior to the study by surgical bilateral removal of ovaries (woman's reproductive system that stores and releases eggs for fertilization and produces female sex hormones), or tubal ligation (getting your "tubes tied") at least six weeks ago.
- Your male partner has already been sterilized. The sterilized male partner should be your sole partner.

- Use of a combination of any two of the following (a+b, a+c, or b+c):
  a. Use of oral, injected or implanted hormonal methods of contraception (in case of oral contraception you should have been using the same pill on a stable dose for a minimum of 3 months before taking study treatment),
  b. Placement of an intrauterine device (IUD) or intrauterine system (IUS),
  c. Use of an occlusive cap (diaphragm or cervical/vault cap) by you, or a condom by your male partner combined with a spermicidal foam/gel/film/cream/vaginal suppository.

Should you become pregnant during the course of the clinical trial, or suspect that you may be pregnant, you must inform your doctor immediately. You must also inform your doctor if you become pregnant within 3 months after ending study treatment.

**Pregnancy Risks - Male**
Men who take part in this clinical trial must ensure that their female partners do not become pregnant either during the trial or within a period of 3 months after the end of study treatment because cancer treatment may lead to deformities in the fetus. In addition, you must agree to refrain from sperm donation from first dose until at least 90 days following the last dose of selinexor. Should your partner become pregnant during the trial or within a period of 3 months of the end of study treatment despite using adequate methods of contraception, it is essential that you inform your doctor.

**Standard of Care Risks**
Your doctor will discuss the risks of routine blood tests, PET/CT scans, MRI, tumor biopsy, and electrocardiogram as these tests and procedures are part of your standard clinical care. Your doctor will also discuss side effects of medications given to prevent, reduce, or treat side effects of the study treatment.

Risk summary
For your safety during this study, call your doctor BEFORE you take any:

- New medications prescribed by your doctor
- Other medications sold over-the-counter without a prescription
- Dietary or herbal supplements

Taking part in this research study may lead to added costs to you. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance company to see what services will be covered and what you will be responsible to pay.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

## Are there reasons you might leave this research study early?

Taking part in this research study is your decision. You may decide to stop at any time. You should tell your doctor if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the researchers, the company supplying drug and funding, or Mayo may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you do not follow the study rules,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

## What if you are injured from your participation in this research study?

**Where to get help:**

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

**Who will pay for the treatment of research related injuries?**

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

## What are the possible benefits from being in this research study?

Taking part in this study may not make your cancer better. While doctors hope that the experimental treatment in this study will be more useful against your cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about selinexor and choline salicylate as a treatment for your cancer. This information could help future patients.

## What alternative do you have if you choose not to participate in this research study?

You do not have to be in this study to receive treatment for your condition. Your other choices may include other anti-cancer drugs and/or radiation therapy if appropriate to your case. You should talk to your regular physician about each of your choices before you decide if you will take part in this study.

## What tests or procedures will you need to pay for if you take part in this research study?

You will not need to pay for tests and procedures which are done just for this research study.

These tests and procedures include:

- Processing and analyzing of research blood tests
- Analyzing of research tissue samples
- If you agree to have a research tumor biopsy done prior to Cycle 3, the study will pay for the US or CT guided biopsy to collect the tissue (Lymphoma, extramedullary myeloma and histiocytic/dendritic cell neoplasm only)
- Study drugs: Selinexor and choline salicylate

However, if selinexor becomes FDA approved for DLBCL or MCL, then after 6 months of complimentary selinexor, the study will no longer provide drug and you will pay for commercial selinexor; Lymphoma SPORE will continue to provide choline salicylate as long as you are on trial.

In addition, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your regular medical care including any co-payments and deductibles.

These tests and procedures include:

- Pregnancy tests, if you are a person of childbearing potential
- Medications to prevent side effects
- Physical exams
- Standard of care blood tests such as hematology and chemistry tests, LDH, HIV screen, and Hepatitis B and C
- ECG
- Photography for skin lesions, if applicable
- PET/CT scans to follow your disease if needed for your cancer
- Tumor tissue biopsies as part of standard of care if needed for your cancerDisease assessments including blood and urine tests: bone survey, whole body low dose CT scan, whole body MRI, or PET/CT; bone marrow aspirate and biopsy, FISH & MRD (for multiple myeloma only).

**If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.**

## Will you be paid for taking part in this research study?

For patients who will have research PK blood samples collected during Cycle 1, you will receive $300 for your stay in Rochester after the completion of Cycle 1. If the research PK samples are only collected on Days 1-3, you will only receive $150.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

There is a very small chance that some commercial value may result from the use of your sample. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

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## Will your information or samples be used for future research?

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research.

Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. Researchers at other institutions may also ask for a part of your information and/or samples for future studies. Unless you indicate otherwise, the future research may be on any topic. No direct benefits to you are expected from the future research. Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information and/or samples by checking 'yes' below, Mayo may send the information and/or samples to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

To support future research, de-identified genetic information may be placed in databases accessible by the internet. Some of the information may be available to anyone using the internet, and some will be released only to approved researchers. Combined study information (including genomic summary results) may be published, but the information will not identify you.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that reidentified information could be used in discriminating ways, and there could be additional unknown risks. We will make every effort to protect your confidentiality.

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**Use of leftover (excess) tissue or an additional fresh tissue collection (for patients with lymphoma, extramedullary myeloma or histiocytic/dendritic neoplasms only):**

If a biopsy is done for clinical reasons during this study, we ask that you donate some of the leftover (excess) tissue for future research. In addition, at the time of a clinical biopsy, we would like to collect an additional tissue sample either before treatment or during the study for future research.

Please respond to the following statements for these optional tissue collections:

1. I permit my information and samples to be stored and used in future research of lymphoma, extramedullary myeloma, or histiocytic/dendritic cell neoplasm at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and samples to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

**Fresh tissue collected for Research Reasons Only (for patients with lymphoma, extramedullary myeloma or histiocytic/dendritic neoplasms only)**

Prior to Cycle 3, we would like to collect a research sample by US or CT guided biopsy for future research:

1. I agree to have an US or CT guided tumor biopsy done:

☐ Yes ☐ No Please initial here: _____Date: _____

**If yes, please complete the following statements:**

2. I permit my information and research sample to be stored and used in for use in future research of lymphoma, extramedullary myeloma, or histiocytic/dendritic cell neoplasm at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit my information and samples to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

4. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

**You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.**

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

## How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Information collected during the study will be coded and stored in a room with restricted access and/or on a computer that is password protected.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

### Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

### Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

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## Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- Public health agencies, if necessary, to complete health reporting requirements
- Karyopharm Therapeutics, the company providing study medications and funding for this study, and Karyopharm's current and future collaborators
- Lymphoma SPORE, the company providing study medications and funding for this study
- A group that oversees the data (study information) and safety of this research.

## How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media) information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

## Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

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## Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study. Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building, PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

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## Enrollment and Permission Signatures

**Your signature documents your permission to take part in this research.**

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

**Person Obtaining Consent**

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature