SUMMARY OF CHANGES

NCI Protocol #: 10212

Local Protocol #: OSU 18296

NCI Version Date: March 26, 2019

Protocol Date: March 26, 2019

I. NCI Rapid Request Amendment (RRA), Dated 03/25/2019

#	Section	Page(s)	Change
1.	Header	All	Updated Header Version Date to match updated protocol version
2.	What risks can I expect from taking part in this study?	6-8	In response to the Request for Rapid Amendment from CTEP dated 03/25/2019, some of the risk information for pinometostat has been updated: If you choose to take part in this study, there is a risk that the pinometostat (EPZ-5676) may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer The pinometostat (EPZ-5676) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. There is also a risk that you could have side effects from the study drug(s)/study approach. Some side effects may make it hard for you to have children. Updated condensed risk profile for pinometastat per revised CAEPR (Version 1.1, January 7,2019:

			• Added New Risk:
			  • Possible: Diarrhea; Electrocardiogram QT corrected interval prolonged; Fatigue; Hypocalcemia; Lymphocyte count decreased; Nausea; Neutrophil count decreased; Rash maculo-papular; Vomiting; White blood cell decreased
			  • Also Reported on Pinometostat Trials But With Insufficient Evidence for Attribution: Alkaline phosphatase increased; Alopecia; Anorexia; Apnea; Cough; Creatinine increased; Dry skin; Dysgeusia; Edema face; Folliculitis; Headache; Hyperkalemia; Hypermagnesemia; Hypernatremia; Hypertension; Hyperuricemia; Hypoalbuminemia; Hypokalemia; Hypomagnesemia; INR increased; Investigations - Other (ejection fraction increased); Irritability; Localized edema; Mucositis oral; Periorbital edema; Pruritus; Respiratory, thoracic and mediastinal disorders - Other (tachypnea); Sore throat; Thrush
			
			• Increase in Risk Attribution:
			  • Changed to Possible from Also Reported on Pinometostat Trials But With Insufficient Evidence for Attribution: Anemia; Hypophosphatemia; Platelet count decreased
			
			• Decrease in Risk Attribution:
			  • Changed to Also Reported on Pinometostat Trials But With Insufficient Evidence for Attribution from Possible: Constipation; Intracranial hemorrhage; Lung infection; Sepsis

Research Study Informed Consent Document

Study Title for Participants: Testing the addition of a new anti-cancer drug, pinometostat, to the usual chemotherapy treatment (cytarabine and daunorubicin) in patients with Acute Myeloid Leukemia

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: "NCI-10212: A Phase 1b/2 study of Pinometostat in combination with standard induction chemotherapy in newly diagnosed Acute Myeloid Leukemia with MLL rearrangement," (NCT#PENDING)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have Acute Myeloid Leukemia (AML), and your cancer has a change in the gene called MLL (lysine methyltransferase 2A).

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can we increase the chance of better treating AML by adding a new drug to the usual combination of drugs?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your AML. The usual approach is defined as care most people get for AML.

What is the usual approach to my Acute Myeloid Leukemia?

The usual approach for patients who are not in a study is treatment with chemotherapy drugs (Cytarabine and Daunorubicin) approved by the Food and Drug Administration (FDA).

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will get pinometostat for up to 35 days, in combination with standard intensive induction chemotherapy.

After you finish your 35 days of pinometostat your doctor will continue to follow your condition and watch you for side effects.. The follow up will occur either until your AML comes back or worsens, or until you get a different treatment for your AML. The follow up will occur during regular clinic visits with your hematologist at least every month.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that the pinometostat along with the regular chemotherapy may not be as good as using the regular chemotherapy alone at treating your cancer.

There is also a risk that you could have side effects from the pinometostat. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about are:

- Low red blood cell counts
- Low or High white blood cell counts

- Low platelets
- Heart Failure
- High liver enzymes
- Low phosphate electrolyte

There may be some risks that the study doctors do not yet know about.

Benefits

This study drug has shrunk or stabilized your type of cancer in a limited number of people with your type of cancer. It is unlikely that it will work in everyone with your type of cancer or help you live longer. This study may help the study doctors learn things that may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (NCI). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

One purpose of this study is to test the safety of a drug called pinometostat, when given in combination with standard chemotherapy for acute myeloid leukemia, at different doses. "Dose" is defined as the amount of drug you get, and there are three possible doses you may receive. Another purpose of this study is to test the good and bad effects of pinometostat, when added to a standard of care treatment for new acute myeloid leukemia. Pinometostat could shrink your cancer, but it could also cause side effects, which are described in the risks section below. The study tests different doses of the drug and doctors hope to see which dose is safer for people and learn if the study drug will remove some or all of the cancer cells from your blood and bone marrow.

There will be about 6-37 people taking part in this study.

What are the study groups?

This study has a screening step. The purpose of this step is to test your tumor to find out if it has a specific gene change. If it does and you meet all the study requirements, then we can assign you to treatment based on these changes. If we find that your blood does not have the genetic changes that are needed for this study, then your doctor will discuss other options for your care.

In the first part of this study (called the "safety run-in phase"), different people will receive different doses of the study drug pinometostat, in combination with a standard of care treatment for acute myeloid leukemia. In the later part of this study (called the "dose expansion phase"), everyone will receive the same dose of pinometostat.

Treatment schedule: You will get pinometostat through a vein in your arm continuously for 35 days. Beginning on the 8th day, you will receive daunorubicin through a vein in your arm daily for 3 days. Also beginning on the 8th day, you will receive cytarabine through a vein in your arm continuously for 7 days.

In the safety run-in phase of this study, there are 2 study groups.

- **Group 1**

  If you are in this group, you will get pinometostat at a higher dose for 7 days, then you will get pinometstat at a lower dose for another 28 days, while you receive the standard of care treatment of daunorubicin and cytarabine.

  There will be about 3-6 people in this group.

- **Group 2**

  If you are in this group, you will get the same dose of pinometostat for 35 days. You will only be put in this group if the higher dose given to the people in group 1 does not cause serious side effects. After the first seven days, you will also receive the standard of care

treatment of daunorubicin and cytarabine.

There will be about 3-6 people in this group.

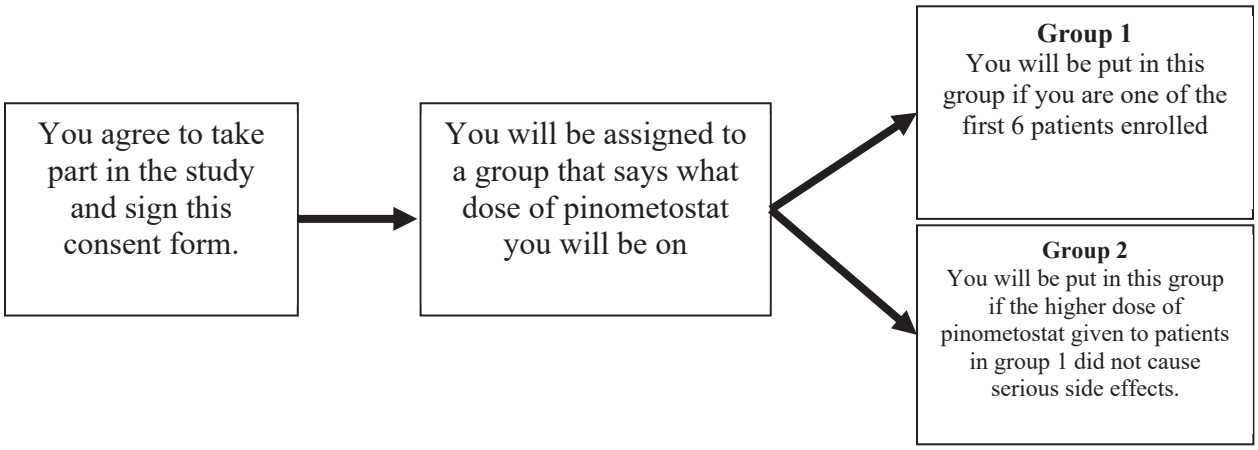
The study doctor will watch each group carefully.

In the dose expansion phase of this study, all participants will receive the same doses of pinometostat as either group 1, or group 2, depending on which was safer. Patients in this group will also receive the same standard of care combination of daunorubicin and cytarabine described above as in the safety run-in phase. There will be up to 25 people in this group.

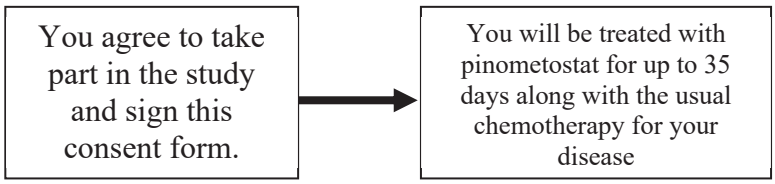
You will not be able to get additional doses of the drug. This drug is not approved by the FDA for treatment of your disease.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right following the lines and arrows. There are two diagrams, one for the early part of the study (the safety run-in phase), where 2 doses are tested, and one for the latter part of the study (the dose-expansion phase), which will study only one dose that was confirmed safe in the first part of the study.

<u>If you participate in the first part of the study:</u>



<u>If you participate in the latter part of the study:</u>



Regardless of which group you will be assigned, your study doctor may treat you again for another 28 days if your disease has not responded to study treatment: This is called re-induction. During re-induction, you will receive pinometostat on days 1-28, daunorubicin on days 1 and 2, and cytarabine on days 1-5.

What exams, tests, and procedures are involved in this study?

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

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

You will have a bone marrow aspiration and biopsy at screening. If you consent to have optional research specimens collected, then an optional bone marrow aspiration and biopsy will be performed after you have finished 7 days of pinometstat. This optional bone marrow biopsy takes small pieces of bone marrow from your body. This is like the biopsy you had that helped diagnose your cancer. This optional bone marrow aspiration and biopsy will help the study researchers find out how pinometostat is working to treat your cancer. You and your study doctor will get the results of this testing. If you agree to take part in the study, you may need to sign a separate consent form for the study biopsy at the hospital or clinic where the biopsy is done.

Fourteen days after starting chemotherapy (21 days after starting pinometostat, the study drug) you will have a bone marrow biopsy to see if all the leukemia is gone. If it is not, your doctors will recommend repeating chemotherapy, but at a smaller dose. This is called “re-induction”.

A bone marrow aspiration will be performed at week 5 to examine your blood counts.

Also, if there is relapse in your disease, another bone marrow aspirate will be performed.

What risks can I expect from taking part in this study?

General Risks

A test result will be used to determine patient eligibility in the study. Because of this, risks include:

- The possibility of incorrectly being found eligible, or
- Receiving an incorrect assignment due to an error in the test, and thus possibly not receiving the best treatment option.

If you choose to take part in this study, there is a risk that the pinometostat (EPZ-5676) may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer.
You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The study drug used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and after you have completed the study medication. Women must use acceptable birth control for 4 weeks after the last dose of study treatment. Men must use a barrier method of birth control for 90 days (3 months) after the last dose of study treatment.

Genetic Testing Risks

As part of this study, we are also studying a study required genetic test that will be performed in the hospital's molecular diagnostics lab. The test is designed to find out if your tumor has the genetic changes that are needed for this study. If it does, we will assign you to a study group based on the genetic changes in your tumor.

Because this genetic test is still being studied, there is a risk that the test results may be wrong. If the test results are wrong, you may be included in this study even though it may not offer the best treatment option for you. Or, you may not be included in this study even though it may offer a good treatment option for you

Bone Marrow Biopsy Risks

Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site. Rarely, an infection can occur. You may sign a separate consent form for the study biopsy that describes the risks in more detail.

Side Effect Risks

The pinometostat (EPZ-5676) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach. Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.

2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

This study is looking at a combination of the usual drugs used to treat this type of cancer plus a study drug. This different combination of drugs may increase your side effects or may cause new side effects.

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible side effects of **Pinometostat** are listed in the tables below. This drug is the experimental part of the study.

POSSIBLE RISKS, SOME MAY BE SERIOUS
• Anemia which may require blood transfusion • Infection, especially when white blood cell count is low • Heart failure which may cause shortness of breath, swelling of ankles, and tiredness • Diarrhea, nausea, vomiting • Tiredness • Change in the heart rhythm • Bruising, bleeding • Rash

Possible side effects of Cytarabine and Daunorubicin are listed in the tables below. These drugs are part of the usual approach for treating this type of cancer:

Possible Side Effects of Cytarabine

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, more than 20 and up to 100 may have:
• Blood clot • Rash • Swelling in the rectum which may cause rectal pain • Diarrhea, loss of appetite, nausea, vomiting • Sores in mouth which may cause difficulty swallowing • Anemia which may cause tiredness, or may require blood transfusions • Fever

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, from 4 to 20 may have:
• Infection, especially when white blood cell count is low • Bruising, bleeding • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Numbness and tingling of the arms and legs • Severe blood infection • Kidney damage which may cause swelling, may require dialysis • Headache • Dizziness • Chest pain • Hair loss • Liver damage which may cause yellowing of skin or eyes • Swelling and redness of the eye

RARE, AND SERIOUS In 100 people receiving Cytarabine, 3 or fewer may have:
• Coma

Possible Side Effects of Daunorubicin

COMMON, SOME MAY BE SERIOUS In 100 people receiving Daunorubicin, more than 20 and up to 100 may have:
• Pink or red colored urine, sweat, or saliva • Nausea, vomiting • Hair loss

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Daunorubicin, from 4 to 20 may have:
• Damage to the heart which may cause shortness of breath, tiredness • Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may require transfusion • Pain and sores in mouth and throat • Diarrhea • Redness and pain at the site of previous radiation • Swelling and redness at the site of injection • Loss of nails • Dark discoloration of the nail, skin

RARE, AND SERIOUS In 100 people receiving Daunorubicin, 3 or fewer may have:
• Cancer of the bone marrow (leukemia) caused by chemotherapy • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat

Additional Drug Risks

The study drug could interact with other drugs and food. However, these are unknown at this point because the drug is so new.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects

- any doctors' visits or hospital stays outside of this study
- if you have been or are currently in another research study

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 4 weeks for women and 90 days (3 months) for men after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your AML.
This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- the costs of daunorubicin and cytarabine
- your insurance co-pays and deductibles

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- Bone marrow aspiration and biopsy done before treatment
- Bone marrow aspiration and biopsy done at relapse (if applicable)
- Bone marrow aspiration on day 8, and the genetic and chemical tests done on this specimen
- Bone marrow aspiration and biopsy on day 21
- Bone marrow aspiration and biopsy at week 5

You or your insurance provider will not have to pay for the pinometostat while you take part in this study: it is provided free of cost to study participants. The preparation and administration of pinometostat is also provided free of cost to study participants.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.
Some of these organizations are:

- The study sponsor and any drug company supporting the study
- The IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.

- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ at _____.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact _____ at _____.

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies hope the results will help other people with your condition in the future. The results will not be added to your medical records and you or your study doctor may not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say “no” to any or all of these studies. There is no penalty for saying “no.” You and your insurance company will not be billed for these optional studies. If you sign up for, but cannot complete any of these studies for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for each of the following studies.

Optional sample collections for known laboratory studies and/or storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Known future studies

If you choose to take part in this optional study, researchers will collect bone marrow for research on AML.

The researched will look at the white blood cells in your bone marrow to see how your AML responded to the study drug and the white blood cells changed from AML cells to normal white blood cells. The researchers will also look to see if the genes and the mechanisms that control the genes in your white blood cells in your bone marrow changed because of the study drug. The researchers will also look at the DNA of your white blood cells to see if certain mutations are there to see how your blood responded to the study drug.

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. A sample of tissue and extra aspirate will be collected from an optional biopsy (the same biopsy that is done after getting pinometostat for 7 days).
2. A small amount of blood will be collected at times when you are already receiving a blood draw for your clinical care
3. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will <u>not</u> include your name or contact information. The researchers do not believe there will be enough genetic information to identify you.

What are the risks in this optional sample collection?

- Because blood will be drawn at times you are getting blood drawn for your clinical care, no extra risk to you is expected
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is

very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance.
- However, the researchers do not plan to generate the type of data ("Whole genome" or "Whole exome") for which this is typically a risk.

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, Dr. James S. Blachly at 614-685-5667. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, Dr. James S. Blachly at 614-685-5667.

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for known future studies:

I agree that my samples and related health information may be used for the laboratory studies described above.

YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature