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 bad things might happen to me if I am in the study?	2	Updated risks for pinometastat, per the revised condensed risk profile based on CAEPR (Version 1.1, January 7,2019)
			• Added New Risk:
			  • Possible: Diarrhea, nausea, vomiting; Tiredness; Change in the heart rhythm; Rash
			• Increase in Risk Attribution:
			  • Changed to Possible from Also Reported on Pinometostat Trials But With Insufficient Evidence for Attribution (i.e., added to the Risk Profile): Anemia which may require blood transfusion; Bruising, bleeding
			• Decrease in Risk Attribution:
			  • Changed to Also Reported on Pinometostat Trials But With Insufficient Evidence for Attribution from Possible (i.e., removed from the Risk Profile): Constipation; Severe blood infection; Bleeding in the brain which may cause headache, confusion

Research Study Assent 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)

- **You are being asked to be in a research study. Studies are done to find better ways to treat people or to understand things better.**
- **This form will tell you about the study to help you decide whether or not you want to participate.**
- **You should ask any questions you have before making up your mind. You can think about it and discuss it with your family or friends before you decide.**
- **It is okay to say "No" if you don't want to be in the study. If you say "Yes" you can change your mind and quit being in the study at any time without getting in trouble.**
- **If you decide you want to be in the study, an adult (usually a parent) will also need to give permission for you to be in the study.**

1. What is this study about?

This study is being done to see if we can better treat AML by adding a new drug to the usual drug treatment and determine if the drug is safe for patients with AML.

2. What will I need to do if I am in this study?

If you decide to take part in this study, you will take a drug called pinometostat, for up to 35 days, in combination with the usual drug treatment. In addition, the doctors will take some bone marrow up to 4 different times from you, using a needle, for testing.

After you finish your 35 days of pinometostat your doctor will continue to follow your condition and watch you for side effects, 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.

If you choose to participate in having an optional research sample drawn on Day 8, 1 teaspoon of blood and 1 teaspoon of bone marrow aspirate will be collected from you for research purposes.

3. Can I stop being in the study?

You may stop being 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.

4. What bad things might happen to me if I am in the study?

You may experience side effects from the Pinometostat which include:

- 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

You may also experience side effects from your usual care:

- Diarrhea, loss of appetite, nausea, vomiting
- Anemia
- Fever
- Rash
- Blood clots
- Mouth Sores

You may experience side effects from the bone marrow collection:

- Small amount of bleeding
- Bruising
- Pain

Risks to an unborn child or a baby:

If you are a female it is important that you do not get pregnant or breastfeed a baby while participating in this study (at least 4 weeks after your last dose of study treatment). If you are a male it is important that you do not father a baby while taking part in this study (at least 90 days after your last dose of study treatment).

5. What good things might happen to me if I am in the study?

You may or may not have any benefit from participating in this study. The information gained from this study could help others with AML in the future.

6. Will I be given anything for being in this study?

You will not receive any payments or reimbursements for participating in this study

7. Who can I talk to about the study?

For questions about the study you may contact _____at_____.

To discuss other study-related questions with someone who is not part of the research team, you may contact _____at _____.

8. Optional Studies that you can choose to take part in

Taking part in these optional studies is your choice. You will not benefit from taking part. If you choose to take part in this optional study, researchers will collect 1 teaspoon of blood and 1 teaspoon of bone marrow on Day 8 for research on AML. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

If you decide you no longer want your samples to be used or if you have questions, you can call the study doctor, _____ at _____.

Please circle either yes or no below to indicate whether or not you would like to participate in the optional research studies:

YES NO

This is the end of the section about optional studies.

Signing the assent form

I have read (or someone has read to me) this form. I have had a chance to ask questions before making up my mind. I want to be in this research study.

Signature or printed name of subject	**Date and time**	**AM/PM**

Investigator/Research Staff

I have explained the research to the participant before requesting the signature above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining assent	**Signature of person obtaining assent**	
	Date and time	**AM/PM**

This form must be accompanied by an IRB approved parental permission form signed by a parent/guardian.