The Cleveland Clinic Foundation
Consent to Participate in a Cancer Research Study

Study title: CASE 1918; Phase I/II Trial of CPX-351 + Palbociclib in Patients with Acute Myeloid Leukemia
Sponsor: Case Comprehensive Cancer Center; Jazz Pharmaceuticals
Principal Investigators: Sudipto Mukherjee, MD – 216-444-0506 (Cleveland Clinic) **After hours phone contact #:** [redacted] or toll free at [redacted], and ask for the oncologist (cancer doctor) that is on call for Cleveland Clinic.
Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at Cleveland Clinic (CC).

Conflict of Interest Disclosure:
One or more of the Investigators conducting this study serve as paid speakers, consultants or advisory committee members for the company that is paying for this research or a company that makes products used in this study. These financial interests are within permissible limits established by the Cleveland Clinic Conflict of Interest Policy. If you have any questions regarding conflicts of interest, please ask your study doctor or call the Institutional Review Board at 216-444-2924.

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?
- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?
We invite you to take part in a research study because you have been diagnosed with acute myeloid leukemia. The purpose of this study is to test the safety and efficacy of the combination of palbociclib plus CPX-351 in patients with acute myeloid leukemia.

CPX-351 is an investigational (experimental) drug that works as formulation of a fixed combination of the antineoplastic drugs cytarabine and daunorubicin. CPX-351 is experimental because it is only FDA approved for the treatment adults with two types of acute myeloid leukemia (AML): newly diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML MRC).

Palbociclib is an investigational (experimental) drug that works by arresting the cancer cell in early stage of its cell cycle. It is approved by the FDA for use in breast cancer, but, in this study, is being

evaluated in a different population of subjects (AML patients), so is considered an investigational (experimental) drug. Palbociclib is experimental because it is not approved by the Food and Drug Administration (FDA) for AML patients.

You will be asked to provide one blood draw for a correlative study. There will be no additional research procedures performed.

Your participation in the research will last about 45 days. After you finish the combination of palbociclib and CPX-351, your doctor will continue to watch you for side effects and follow your condition bimonthly for up to 2 years, depending on your condition.

More detailed information can be found under the section labeled: "Information on the

Research." **Why might you choose not to participate in this research study?**

There may be discomforts, side effects, and risks to using the palbociclib plus CPX-351 treatment combination that we do not know yet. Sometimes during a study, the sponsor may learn new information about the study drug and the risks, which the study doctor/staff will tell you about in a timely manner. This new information might make you change your mind about being in the study. The study drugs may not be better, and could possibly be worse than the usual approach for your cancer. Additionally, you may lose time at work or home and spend more time in the hospital or the doctor's office than usual. You also may be asked sensitive or private questions which you normally do not discuss.

More detailed information about the risks of this study can be found in the section labeled

"Risks." **Why might you choose to volunteer for this study?**

We cannot know if you will have any benefit as a result of your participation in the study; it is possible the study treatment may improve your condition, which may give you relief from some symptoms or improve your quality of life. However, it is possible that your condition could worsen. Your participation in this study will help to obtain information about treating subjects with acute myeloid leukemia.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?
If you do not wish to take part in this research study, your study doctor will discuss alternative treatment options with you, including their benefits and risks. These may include:

- · The usual approach to treating acute leukemia
- · Taking part in other investigational studies if they are available
- · Supportive care which does not treat the leukemia but treats the symptoms

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?
The purpose of this study is to evaluate the safety and tolerability of Palbociclib in combination with CPX-351 and evaluate the effectiveness of Palbociclib in combination with chemotherapy as measured by overall response rate (ORR), i.e. complete response (CR) and CR with incomplete blood count recovery (CRi). Complete response (CR) is considered when the blasts percentage in the bone marrow < 5% and counts improved to certain level. CR with incomplete blood count recovery (CRi) is considered one the blasts are <5% but the counts did not meet criteria for complete remission. Both terms confirm remission.

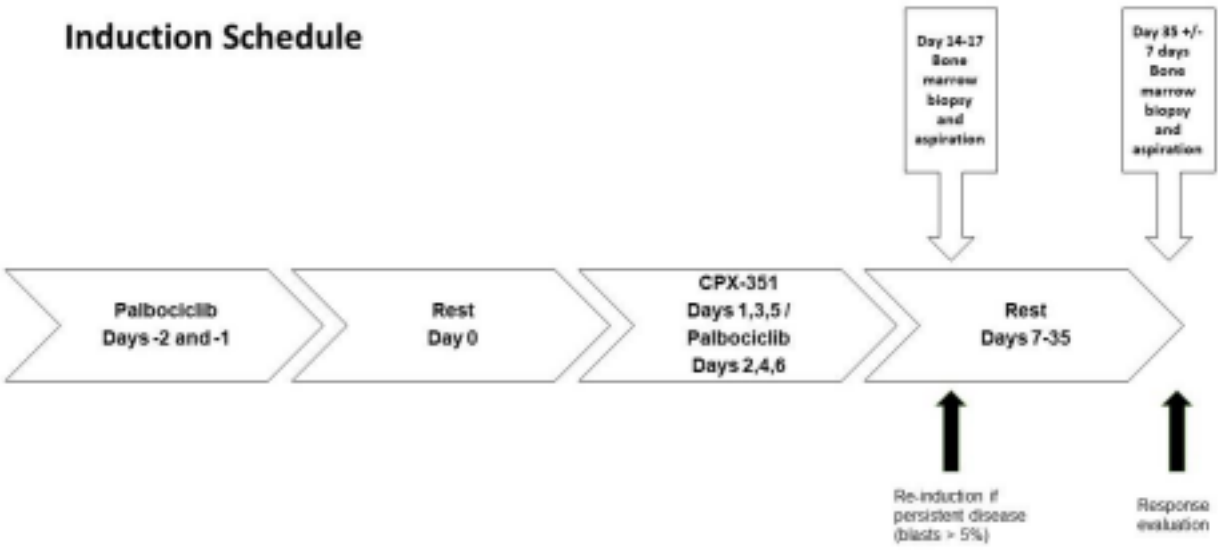
How Many People Will Take Part in this Study?
Approximately 35 people will take part in this study at Cleveland Clinic.

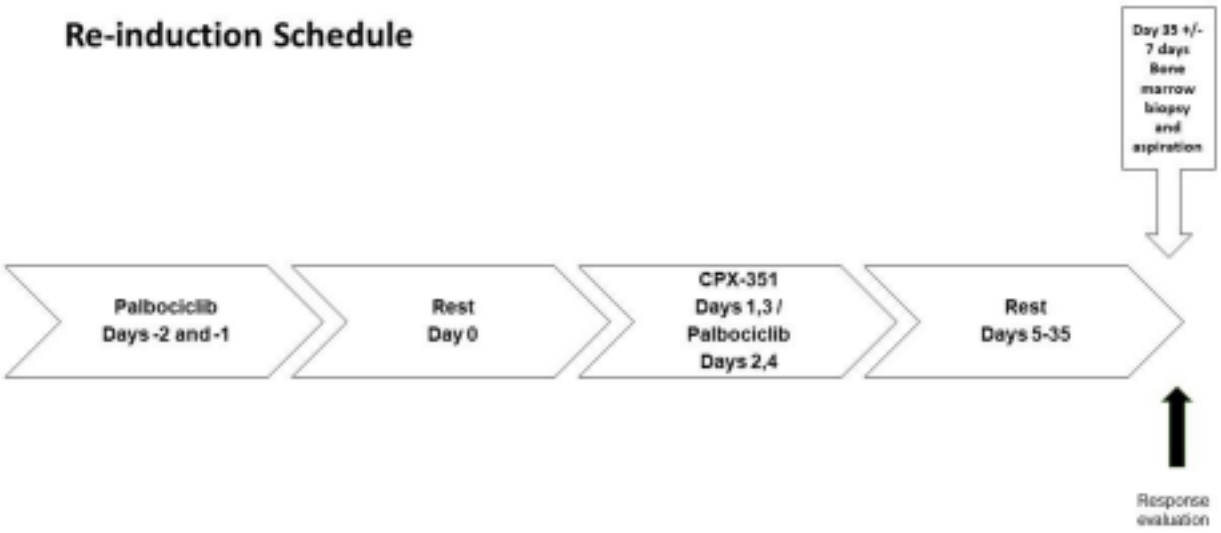
What is involved if you decide to take part in this research study?

Phase 1 Dose Escalation Studies
This portion of the study has been completed. The recommended safe dose of Palbociclib, the study drug, when given with chemotherapy was identified (125 mg) and will be used for treatment in the Phase II portion of the study.

Phase II
This portion of the study will evaluate how well Palbociclib, the study drug, when given with chemotherapy, will effectively treat the leukemia. Each patient in this part of the study will receive the same dose of Palbociclib.

To find out what will happen to you during this study read the charts below. Start reading at the left side and read across to the right, following the lines and arrows. Your first course of treatment, or "induction", will be completed as shown below. Depending on your response to this treatment, you may or may not have a second course, or "re-induction". Please ask your study doctor any questions you may have regarding this treatment plan.





All study participants in Phase II will get the same study intervention. It will include the usual chemotherapy (CPX-351). All study participants will also get the study drug (Palbociclib) based on the Phase 1 findings.

Induction Calendar

Period	Screening Period[A]	Treatment Period

Day		-2[J]	-1	0	1	2	3	4	5	6	7	8	9	10
Informed consent form	X													
History and physical exam	X													
Concomitant Medication[B]											X			
ECOG performance status	X													
Hematology	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum Chemistry	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Uric Acid	X	X	X	X	X	X	X	X	X	X				
Phosphate Level	X	X	X	X	X	X	X	X	X	X				
Magnesium Level	X	X	X	X	X	X	X	X	X	X				
Pregnancy test	X													
ECG[G]	X	X	X	X	X	X	X	X	X	X				
ECHO or MUGA	X													
Vital sign	X	X	X			X		X		X				
Bone marrow biopsy	X													
Bone marrow aspirate	X													
Survival Follow up														
Record RBC/ platelets transfusion	X													
Disease response assessment														
Disease related follow up														
Correlative Samples	X													
LDH/Tumor Lysis Syndrome	X													
AE Assessment[F]											X			
Study Drugs														

Palbociclib		X	X			X		X		X				
CPX-351					X		X		X					

A: Screening period is defined as the time period from the day of consent to start of study therapy.
B: Con Meds will be collected for medications that were administered because of an AE or medical history
C: Day 14 bone marrow biopsy/aspirate have a +3 days window; this is not required during re-induction
D: Day 35 bone marrow biopsy/aspirate have a +/- 7 days window
E: Follow up occurs every 6 months (+/- 7 days window) for 2 years after EOT visit
F: SAE follow up must be reported through 30 days after last dose
G: Skip palbociclib dose if QTcB > 480ms
H: Does not need to be repeated at EOT if being done same day as Day 35 bone marrow biopsy/aspirate
I: To be performed on same day as Day 35 biopsy
J: Day -2 pre-dose assessments do not need to be repeated if being done same day as screening. If the same assessments are being used for both screening and day -2, the data should be entered at screening in the database.

Re-Induction Calendar

Period	**Treatment Period**														
Day	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12
History and physical exam															
Concomitant Medication[B]											X				
ECOG performance status															

Hematology	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Serum Chemistry	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Uric Acid	X	X	X	X	X	X	X									
Phosphate Level	X	X	X	X	X	X	X									
Magnesium Level	X	X	X	X	X	X	X									
ECG[G]	X	X	X	X	X	X	X									
Vital sign	X	X			X		X									
Bone marrow biopsy																
Bone marrow aspirate																
Survival Follow up																
Disease response assessment																
Disease related follow up																
AE Assessment[F]	X															
Study Drugs																
Palbociclib	X	X			X		X									
CPX-351				X		X										

CCF IRB #: 19-347
Approval Date:
8/26/2021 Expiration
Date: 3/28/2022

Study procedures

The following describes all the procedures you can expect to have during the study. Not all procedures will be done at every visit. The study doctor/study staff will discuss this with you in more detail.

Informed Consent:

The study doctor/staff will talk to you about the study and you will decide if you want to join. This will be done during the Screening visit.

Review medical history:

You will discuss your current and past health with the study doctor/staff. This will be done during the Screening visit.

Review of medications:

You will talk with the study doctor/staff about any medicines you take. This will be done during the Screening, Treatment and Follow Up visits.

Physical examination:

The study doctor/staff will check your body for general health. This will be done during the Screening and Treatment visits.

Vital signs:

The study doctor/staff will take your pulse, temperature, and blood pressure. This will be done during the Screening and Treatment visits.

ECG (Electrocardiogram):

Sticky patches that are connected to a machine that shows the electrical activity of your heart, are placed on your chest, arms and legs. This will be done during the Screening visit and maybe during Treatment visits if your Study Doctor advises you need this test.

Blood draw/tests:

The study doctor/staff will draw blood from a vein in your arm, or may draw blood samples from a central catheter placed in the upper chest. You may get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint and, in rare cases, can get an infection.

Sometimes you will need to repeat a blood test.

Your blood will be used to check for:

- Your general health
- Disease evaluations
- How your body handles the study drug
- Pregnancy (if you are a female who could get pregnant.)
- Scientific Research
    - 10mL of your blood will be taken for exploratory studies

Bone Marrow Aspirate/Biopsy:

An area of bone (usually pelvis) will be made numb by injecting a local anesthetic, and then a needle will be inserted into the bone. A small amount of bone and bone marrow will be removed. The bone marrow aspirate/biopsy will be used for disease evaluations, as well as Scientific/Genetic Research. This will be done during the Screening, Treatment and possibly Follow Up visits.

How will my specimens be used?
Your samples collected for this research will be analyzed for the study. As part of the analysis, the research might include whole genomic sequencing. This means that researchers may look at your sample to learn about your genes (DNA). There are different ways to look at your DNA. Researchers often use a technology called sequencing to look at your DNA. Sequencing "reads" each letter of the DNA and finds changes (also called "variations" or "mutations") in your genes that may cause disease or affect how your body reacts to a certain disease.

The research done with your blood may lead to the development of new products in the future. You will not receive, either now or in the future, any compensation, royalty, or other financial benefits resulting from any product, procedure, or other items developed from studying your sample(s).

Will I be notified of the results of the tests/studies on my samples?
When samples are collected and analyzed, there is the chance of finding something that may be important for your care. You will be informed of any results that are relevant to your clinical care.

The research may find that you have an abnormal gene or gene product (RNA or protein) which indicates a risk for developing a disease at some time in the future. These results may also indirectly provide information about your entire family. This information will be provided to you

and your physician. A genetic counselor is available to you to discuss the results. The cost of a genetic counselor WILL NOT be paid by the research.

2. RISKS

What are the risks of participating in the research study?

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. While the chance that someone could access and misuse your information is believed to currently be very small, it is possible that the risk may increase in the future as people find new ways to access information.

Side effects from the drugs are listed below. Some side effects are temporary, some long-lasting or permanent, some are mild and some may be severe, and some may lead to death.

Possible side effects of CPX-351:

COMMON, SOME MAY BE SERIOUS
In 100 people receiving CPX-351 more than 10 and up to 100 may have:
▪ Anemia (even requiring blood transfusions) ▪ Neutropenia (low white blood cell count, which increases risk of infection) ▪ Fatigue ▪ Diarrhea ▪ Nausea ▪ Constipation ▪ Hemorrhage ▪ Rash ▪ Edema (swelling) ▪ Mucositis (irritation of mucous membranes, like in the mouth, nose, or vagina) ▪ Musculoskeletal pain

- Dyspnea (shortness of breath)
- Arrhythmia
- Pneumonia
- Abdominal Pain
- Sleep Disorder
- Cough
- Chills
- Headache
- Dizziness

CCF IRB #: 19-347
Approval Date: 8/26/2021 Expiration Date: 3/28/2022

- Non-conduction Cardiotoxicity (cardiotoxicity or damage to the heart caused by the anthracylcine doxorubicin)
- Fungal infection
- Upper respiratory infection (excluding fungal)
- Hypoxia (low amount of oxygen in the blood)
- Hypertension
- Hypotension
- Vomiting

- Chest Pain
- Decreased appetite
- Bacteremia (infection in the bloodstream, excluding sepsis)

- Delirium
- Pyrexia (fever)
- Pleural effusion (fluid around the lungs)
- Anxiety
- Pruritus (itching)
- Sepsis (excluding fungal)
- Hemorrhoids
- Petechiae (red spots on the skin)
- Renal (kidney) insufficiency, even to the point of needing dialysis
- Transfusion reactions
- Visual impairment (except bleeding)
- Catheter/device/injection site reaction
- Prolonged low platelets (increased risk for bleeding, and may need platelet transfusions)
- Prolonged low neutrophil count
- Hair loss

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving CPX-351 more than 5 may have:

CASE 1918
Consent Version: 7/21/2021

CCF IRB #: 19-347
Approval Date: 8/26/2021
Expiration Date: 3/28/2022

- Hyponatremia (low sodium)
- Hypokalemia (low potassium)
- Hypoalbuminemia (low albumin)
- Hyperbilirubinemia (jaundice)
- Alanine aminotransferase abnormalities (indicating liver damage)

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving CPX-351 less than 10 may have:

- Ear and labyrinth disorders: Deafness, Deafness unilateral
- Eye Disorders: Eye conjunctivitis, Dry eye, Eye edema, Eye swelling, Eye irritation, Eye pain, Ocular discomfort, Ocular hyperemia (redness of the eyes), Periorbital edema (swelling around the eyes), Scleral hyperemia (redness of the white part of the eyes)
- Gastrointestinal disorders: Dyspepsia (upset stomach)
- Psychiatric disorders: Hallucinations
- Respiratory, thoracic and mediastinal disorders: Pneumonitis (irritation of the lungs)

CCF IRB #: 19-347
Approval Date: 8/26/2021
Expiration Date: 3/28/2022

In addition to side effects outlined above, you may also experience the possible side effects of Palbociclib listed below.

COMMON, SOME MAY BE SERIOUS
In 100 people receiving Palbociclib more than 20 and up to 100 may have:
▪ Anemia ▪ Neutropenia ▪ Fatigue ▪ Diarrhea ▪ Nausea

OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving Palbociclib from 5 to 10 may have:

- Decreased appetite
- Constipation
- Vomiting
- Rash
- Flatulence
- Abdominal pain
- Shortness of breath
- Fever

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving Palbociclib from 5 to 10 may have:

- Cough
- Back pain

RARE, AND SERIOUS

In 100 people receiving Palbociclib 5 or fewer may have:

- Hair loss
- Headache
- Nosebleed
- Muscle spasm
- Upper respiratory tract infection
- Dry mouth
- Itching
- Dizziness
- Abdominal swelling
- Chills
- Runny nose

Inflammation of the lungs

Palbociclib—used to treat some patients with advanced breast cancer—may cause rare but severe inflammation of the lungs. According to the FDA, patients should notify their health-care

CCF IRB #: 19-347
Approval Date: 8/26/2021
Expiration Date: 3/28/2022

professional right away if they have any new or worsening symptoms involving their lungs, as they may indicate a rare but life-threatening condition. Symptoms to watch for include difficulty or discomfort with breathing and shortness of breath while at rest or with low activity.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a disorder characterized by headaches, mental status changes, visual disturbances, and/or seizures. PRES often occurs in patients with renal disease, such as hypertension, vascular and autoimmune diseases, exposure to immunosuppressive drugs (for example chemotherapy), and organ transplantation. If recognized and treated quickly, symptoms usually resolve within a week, and the changes seen in magnetic resonance imaging (MRI) resolve in a matter of days to weeks. A patient on this clinical trial developed this complication and it was determined to be possibly related to the combination of study drugs.

Unknown Risks

There may be risks or side effects related to the study drug/device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

Reproductive Risks

There may be unforeseen risks to an unborn child associated with your taking palbociclib and CPX-351. Therefore, if you are capable of giving birth to or fathering a child, you and your sexual partner should use adequate birth control measures while you are in the study. These measures may include abstinence, oral contraceptives (birth control pills), IUD, diaphragm, approved hormone injections, condoms, or documentation of medical sterilization. Discuss with your doctor which birth control measures are acceptable.

If you are unwilling to do this, we ask that you not participate in this study. Pregnancy tests will be performed on all women of child-bearing potential before beginning the study and during the study each day for the first eight days. If you or your sexual partner become pregnant while taking part in this study you must notify the study doctor immediately.

Confidentiality Risks

There is a potential risk of loss of confidentiality of your data. Efforts will be made to keep your information confidential through the use of the following safeguards: use of codes, storage in a password protected computer accessible only by the research team**.** If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

Blood Draw

The insertion of the needle to draw blood can be painful; however, the discomfort is brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

Bone Marrow Biopsy

There are also risks associated with taking samples of your bone marrow. Your study doctor will insert a needle into your hip or breast bone to withdraw a sample of fluid containing bone marrow cells. The risks of bone marrow sampling commonly include discomfort, pain, redness, swelling, and/or bruising where the sample is taken from your hip or chest. Sometimes bleeding can occur at the place where the sample is drawn. Fainting and infection can happen, but rarely. Many patients also experience soreness or stiffness in the hips for several days after the procedure.

3. BENEFITS

Participation in this study may help to improve your condition, but it is also possible that your

condition may worsen. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have a similar medical problem in the future.

4. COSTS

Are there any costs to you if you participate in this study?
The following research study activities are being done only because you are participating in this research study and **will be paid for by the study sponsor** and will not be billed to you or your health insurance plan. These "research only" activities include: additional bone marrow biopsies outside of protocol requirements; electrocardiograms on scheduled days between day -2 and day 14 (see study calendar); administration of the study drugs; correlative blood sample and the bone marrow send out at screening.

Some of the services you will receive during this research study **are considered to be conventional routine clinical services that you would have received even if you were not participating in the research** study and will be billed to you or your health insurance plan. Examples of these routine services include: all blood samples used for labs such as complete blood count, complete metabolic panel, magnesium, phosphorus, uric acid, and pregnancy tests (if applicable); select bone marrow biopsies at screening and at end of treatment; any additional medication outside of the study drug, hospitalizations, and any radiographic tests. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

5. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?
If you believe that you are injured as a result of the research procedures being performed, please immediately contact the study doctor.

CCF IRB #: 19-347
Approval Date: 8/26/2021
Expiration Date: 3/28/2022

If injury occurs as a result of your involvement in this research, medical treatment is available from Cleveland Clinic or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Further information about research-related injuries is available by contacting the Cleveland Clinic Institutional Review Board at (216) 444-2924.

6. HIPAA AUTHORIZATION
Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to Sudipto Mukherjee, MD, and the research study staff at Cleveland Clinic for the purposes of this research and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- Cleveland Clinic, its study monitors and representatives
- Funding/Drug Support: Jazz Pharmaceuticals
- Case Comprehensive Cancer Center members and collaborators
- The Food and Drug Administration;
- The Department of Health and Human Services;
- The National Cancer Institute (NCI);
- Other Institutional Review Boards;
- Data Safety and Monitoring Boards;

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

Sudipto Mukherjee, MD
Case Comprehensive Cancer Center
Cleveland Clinic
9500 Euclid Ave.
, OH 44195

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside the Cleveland cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic will not use your information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board

(IRB) assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

What will happen to your information that is collected for this research?
Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it for research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

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

7. QUESTIONS

Who do you call if you have any questions or problems?
If you have any questions, you can ask the Principal Investigator and/or research staff at [redacted]

Emergency or after-hours contact information

If you are a Cleveland Clinic patient, you should contact the page operator at [redacted] or toll free at [redacted], and ask for the oncologist (cancer doctor) that is on call.

Where Can I Get More Information?
If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: concerns regarding the study, research participant's rights; research-related injury; or other human subjects issues, you may contact the Institutional Review Board (IRB) at Cleveland Clinic IRB 216-444-2924.

You may call the National Cancer Institute's Cancer Information Service at: 1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

▪ For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/ ▪ For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

8. VOLUNTARY PARTICIPATION

What are your rights as a research participant?
Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed.

In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

Can I withdraw my samples?
If you agree to allow your blood to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact the Principal Investigator in writing and ask to withdraw your permission for your identifiable blood to be used for future research. The mailing address is,

Sudipto Mukherjee
9500 Euclid Ave, [redacted]
Cleveland, OH 44195

CCF IRB #: 19-347
Approval Date: 8/26/2021
Expiration Date: 3/28/2022

At that time we will ask you to indicate in writing if you want the unused identifiable blood destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

9. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____

Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date