5/25/2021

MCW/FH IRB

# Medical College of Wisconsin and Froedtert Hospital INTRODUCTION TO THE INFORMED CONSENT

Name of Subject:

IIT-Michaelis: A multi-institutional, phase IV project to study the feasibility of safely managing patients receiving induction with liposomal daunorubicin and cytarabine (CPX-351) for acute myeloid leukemia (AML) in an outpatient environment

Subject Consent

Laura Michaelis, M.D. Department of Medicine Division of Hematology and Oncology Medical College of Wisconsin & Froedtert Hospital 9200 W Wisconsin Ave Milwaukee WI 53226 414-805-6700

You are invited to take part in this research. You can decide whether to take part in this project or not. You are free to say yes or no. If there is anything that you do not understand, please ask questions.

# **Definitions**

**CPX-351** – also called Vyxeos, an FDA approved induction therapy for AML

Induction Therapy – the first treatment given for a disease

**Inpatient/Outpatient –** describes the location where you stay after receiving your treatment, in the hospital (inpatient) or at home (outpatient)

**Count Recovery** – when the blood cell counts, including your infection-fighting cells and bleeding-prevention cells, return to safe levels

Medical College of Wisconsin & Froedtert Hospital <b>Informed Consent for Research</b> Clinical Interventions template - Version: March 30 IRB Protocol Number: 34597 IRB Approval Period: 5/25/2021 – 5/24/2022	EFFECTIVE 5/25/2021 MCW/FH IRB	
<b>Purpose</b> This project is being done to study the drug CPX-351 when given in an outpatient setting and to assess the quality of life and management of health-related issues for you and your caregiver.	1. You will be about 3 mo	<u>Length</u> in this research project for nths.
ProceduresList of visits:• Screening Visit• Total Number: 1• Total Time: 2-4 hours• Treatment visits• Total Number: 4-6• Total Time: 2-5 hours per visit• Study Visits until Count Recovery• Total Number: about 1-3• Total Time: about 1-3 hours per visit• Total Time: about 1-3 hours per visit• Total Number: 1-2• Total Time: 1-2 hours each• Total Time: 1-2 hours each• Total Time: 1-2 hours each• Drocedures that will occur at various visits:• Bone marrow biopsy• Routine blood tests• Drug infusion• Echo/MUGAMedical history• Physical exam• ECG• Urinalysis• Questionnaires	side effects. Th introduction co potential resea <b>CPX-351 risks</b> Bleeding Fever Rash Swelling Nausea Sores in f Diarrhea Constipat Muscle pa Tiredness Stomach Difficulty Headache Cough	the mouth or throat tion ain s Pain breathing e ed appetite heartbeat nia ection

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We don't know if this project will help you. Your condition may get better but it could stay the same or even get worse.

# My Other Options

You do not have to join this project. Your other options may include:

- 1. Joining a different project
- 2. Getting no treatment for this condition

If you have more questions about this project at any time, you can call Dr. Michaelis at 414-805-6700.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

**Benefits** 

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# CONSENT TO PARTICIPATE IN RESEARCH

# A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you have been newly diagnosed with acute myeloid leukemia (AML) and are eligible for treatment with CPX-351 therapy.

A total of about 120 participants and 120 or more of their caregivers are expected to participate in this research nationally including about 20 participants and 20 or more of their caregivers at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the project is Laura Michaelis, MD in the Department of Medicine. A research team works with Dr. Michaelis. You can ask who these people are.

Jazz Pharmaceuticals, a drug company, is funding the research.

# A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this project, you do not have to stay in it. You may stop at any time.

A research project is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the research procedures, tests and visits follow a set plan that must be kept.

#### A3. WHY IS THIS PROJECT BEING DONE?

CPX-351, an induction treatment for AML is approved by the U.S. Food and Drug Administration. Traditionally, treatment is provided in an inpatient environment where patients stay in the hospital for between three to five weeks. This study is designed to assess CPX-351 given in an outpatient setting where treatment is given in the hospital, but the patient goes home every day after the treatment is completed. Patients continue in that setting as long as they respond well and are considered safe to be treated as an outpatient.

The purpose of this project is to study the feasibility of giving CPX-351 to adult patients with AML as an outpatient therapy. This study will also monitor the experiences of both you and your caregiver on the management of side effects and your quality of life.

#### **B1. WHAT WILL HAPPEN IF I PARTICIPATE?**

Before any study tests or procedures are done, you will be asked to sign this consent form. The study staff will discuss the study with you and answer your questions. If you decide to join the study, some screening tests will be done first to see if you are eligible.

All of these tests and procedures are considered "standard of care" which means that they would be done even if you do not take part in the research study. If you have had some of these tests or procedures recently, they may not have to be repeated.

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#### Screening procedures:

The screening procedures and assessments must be completed prior to starting the study treatment to confirm that you are eligible for this study.

#### Completed within 14 days prior to treatment

- Bone marrow biopsy
- ECHO/MUGA (cardiac assessment)

# Completed within 7 days prior to treatment

- Medical History which includes questions about your health, and current medications
- Physical Exam which includes your vital signs
- Your performance status that evaluates how you are able to carry on with your usual daily activities
- Routine blood tests
- Urinalysis
- Serum or urine pregnancy tests for women of child bearing potential

#### Nurse Teacher Education Program

You and your caregiver will be enrolled in an education program. This must be completed within 7 days prior to treatment. This program will provide education on the outpatient monitoring and reporting requirements including the completion of subject diaries that will allow you to keep track of your symptoms, medication use, and temperature on a daily basis. You will also be provided additional educational materials to guide you with this monitoring.

If all above criteria are met, then you will be able to start the study. If the screening information shows that you cannot be in the research study, your study doctor will discuss other options with you.

#### **Summary of Treatment Procedures**

#### Week 1 - Induction Therapy:

You will come to the clinic for days 1 through 6 the first week of the study.

#### Days 1, 3 and 5:

Prior to your infusion of CPX-351, you will have the following:

- Physical exam which includes your vital signs
- Routine blood tests
- Review of any side effects that you may be experiencing
- Completion of questionnaires asking about your symptoms and your health with a member of the study team (Day 1)
- Review of your study diary

Once these tests and assessments are completed, you will receive your infusion of CPX-351. The infusion should take approximately 90 minutes.

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# Days 2, 4 and 6:

On days 2, 4 and 6 you will not receive an infusion. For these visits you will have the following:

- An Oncology Nurse will complete an assessment
  - This will be done on the phone on days 2 and 4
  - On day 6 you will come to the clinic to have blood drawn for routine testing, to see the nurse and have vitals taken
- Review of any side effects that you may be experiencing
- Review of your study diary

# Weekly, Beginning with Week 2 Until Count Recovery

Until your cell count recovers, you will come to the clinic three times a week. On two of the days between these clinic visits, you will receive phone calls from your oncology nurse.

Three times per week you will have the following at the clinic:

- An Oncology Nurse will meet with you and complete an assessment
- Review of vital signs
- Review of any side effects that you may be experiencing
- Routine blood tests
- Review of your study diary
- Completion of questionnaires asking about your symptoms and your health (once only between day 7-10)

Once per week (may occur during one of the above visits) you will have the following at the clinic:

- Physical exam which includes your vital signs
- Review of any side effects that you may be experiencing
- Review of your study diary

# Two times per week you will have the following:

You will be called by the Oncology Nurse. During the phone call the Oncology Nurse will review your study diary with you and see if any needs or concerns arise. This may continue until your blood counts recover or until 90 days after the first infusion of CPX-351 (whichever comes first).

# 30, 60, and 90 Days from Day 1 of CPX-351 Induction

You will come to the clinic for the following:

- Recent medical history which includes questions about your health, and current medications
- Physical Exam which includes your vital signs
- Your performance status which evaluates how you are able to carry on with your usual daily activities
- Review of any side effects that you may be experiencing (only on day 30 and day 60)
- Completion of questionnaires asking about your symptoms and your health (only on day 30 and day 60)
- Review of your study diary (until count recovery or day 60, whichever occurs first)

At any time when you or your doctor don't feel that it is safe for you to be an outpatient, then you will be admitted to the inpatient service. If your doctor finds any concerning medical information or findings, then they will recommend admission to the hospital for treatment.

If you are admitted to the hospital and improve and your doctor feels that it is safe to discharge you, you may remain on study and be cared for, again, in the outpatient environment.

# **B2. HOW LONG WILL I BE IN THE PROJECT?**

You will be in this research project for about 3 months.

You will take the CPX-351 for 1 week. After you have finished treatment, we will follow you until 90 days after the first day of CPX-351 treatment to monitor your health.

# **B3. CAN I STOP BEING IN THE PROJECT?**

You are free to withdraw from the project at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the research doctor.

- The research doctor can tell you about the effects of stopping, and you and the research doctor can talk about what follow-up care would help you the most.
- You might be asked to come back for one more visit to check your health.

The research doctor may take you out of this project at any time. This would happen if:

- They think it is in your best interest.
- You do not follow the project rules.
- The whole project is stopped.

If this happens, the research doctor will tell you.

# **B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE PROJECT?**

- You must bring your study diary to each clinic visit.
- You must live within 45 minutes from the clinic
- You must have a reliable caregiver who signs a separate caregiver consent
- You must have reliable, working telephone access

# C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

There are risks to taking part in any research project. There is a risk that you may get a drug that does not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet, from CPX-351 itself, or how it combines with other drugs you are taking. If we learn about new important side effects, we will tell you.

We watch everyone in the project for problems (side effects). You need to tell the research doctor or a member of the research team immediately if you experience any problems, side effects, or changes in your health. If you have severe side effects, call Dr. Michaelis immediately at 414-805-6700. In an emergency, call 911.

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#### C2. RISKS OF CPX-351

The CPX-351 itself may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.

Drugs can affect individuals in different ways. Complications of some of the side effects below may lead to life-threatening events and possibly death.

The most common side effects related to CPX-351 include:

- Bleeding
- Fever
- Rash
- Swelling
- Nausea
- Sores in the mouth or throat
- Diarrhea
- Constipation
- Muscle pain
- Tiredness
- Stomach Pain
- Difficulty breathing
- Headache
- Cough
- Decreased appetite
- Irregular heartbeat
- Pneumonia
- Blood infection
- Chills
- Sleep disorders
- Vomiting

There is increased risk by joining this study because this drug is usually given while inpatient and you will receive this drug while outpatient. Medical staff will not be able to observe you at all times like in the inpatient hospital setting. To help decrease this risk, the study has a few additional requirements:

- Nurse assessments will be done over the telephone on days you don't see your doctor
- You need to live close to the hospital, so you can come in for more checks if needed
- You need to have a caregiver who is qualified to help you as needed
- You will participate in a study-specific education program

# **C3. OTHER RISKS OF THIS RESEARCH PROJECT**

Other procedures that are part of the research also involve some risks:

#### **Risks of Outpatient Treatment:**

The most important health risk from this study is that something could happen while you are an outpatient, i.e. a severe infection or bleeding event, that needs immediate care or treatment.

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# **Questionnaires:**

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. (If you become upset, please let us know and we can give you information about individuals who may be able to help you.)

# Risks of Bone Marrow Aspirate/Biopsy Collection:

Bone marrow is collected using a needle under local anesthesia to aspirate (draw out) marrow tissue from the inside of your bone marrow aspirate (usually pelvic or hipbone). Biopsy refers to removal of a piece of tissue that does not cause any serious problems. The risks on bone marrow biopsy and aspirate include pain, bleeding, bruising, and/or discomfort at the biopsy site. Infection is also possible but rare.

# Risks of an Echocardiograms (ECHO):

For the ECHO, an ultrasound probe is pressed against your chest to look at the structure and function of your heart. You may have some discomfort when the wand is pressed against your chest in order to take pictures of your heart.

# Risks of a Multiple Gated Acquisition Scan (MUGA):

A MUGA Scan takes images of the beating heart to see how well your heart is pumping blood. A small amount of radioactive material will be injected into your vein and bind to your red blood cells (blood cells that carry oxygen throughout your body) in order for the special camera to take pictures of how the blood moves through your heart. You will be asked to lie very still during this scan, because any movement can cause the images to be blurry. There may be some discomfort from having to lie still during the length of the procedure. Allergic reactions to the radioactive material are rare but may occur. The injection of the radioactive material may cause some slight discomfort.

# **Risks of IV Injections:**

For an IV injection, a needle is inserted into your vein. For most people, needle sticks for IV injections do not cause any serious problems. The use of an IV may cause discomfort, irritation, mild bruising, bleeding, and rarely infection, nausea (stomach upset), and lightheadedness (feeling faint).

# **Risks of Blood Tests:**

For most people, needle punctures for blood draws do not cause any problems. However, sometimes they may cause discomfort, irritation, mild bruising, bleeding, and rarely infection, nausea (stomach upset), and lightheadedness (feeling faint).

# **C4. REPRODUCTIVE RISKS**

# Risks to women who could become pregnant

The drug in this project might affect a baby, before or after the baby is born. We do not know if the drug cause(s) harm to a baby, so we do not want anyone who might be pregnant to enter the project. You should not become pregnant or nurse a baby while in this project. You must tell

the research doctor right away if you think you are pregnant. You will be asked to have a pregnancy test to be sure you are not pregnant at the start of the project.

If you become pregnant during the project, you will be withdrawn from treatment for safety reasons. If you become pregnant while you are taking this experimental drug or within 3 months after you have stopped taking it, we ask that you inform the research doctor immediately. The research doctor will ask you for written permission to obtain information from you or your obstetrician on your pregnancy and the health of the baby.

# Risks of fathering a child

You should not father a baby while taking part in this project because it is unknown if the drug could affect a baby. If your partner is able to become pregnant, one or both of you must use some form of effective birth control. You must tell the research doctor right away if you think your partner is pregnant.

If you think that you have fathered a baby while you are taking this experimental drug or within 3 months after you have stopped taking it, we ask that you inform the research doctor immediately. At that time, the research doctor will ask permission of your partner for the use and disclosure of her health information regarding the pregnancy. She will be asked to sign a separate consent form. She can choose to do this or not. She will be asked to sign this form to allow your research doctor to contact her obstetrician to collect information on the progress of the pregnancy and its outcome. The research doctor will make this information available to the sponsor for safety monitoring.

# Birth control methods for all subjects

Check with the research doctor about the birth control methods needed for this project and how long to use them. Some methods might not be good enough for this project. If you are having sex that could lead to pregnancy, you should use birth control while you are in this project.

You must agree to use two acceptable methods of birth control. This may include the following:

- Not having vaginal sex (abstinence)
- Taking birth control pills orally
- Having birth control shots or patches such as Depo-Provera
- Use of an intrauterine device (IUD)
- Use of diaphragm with contraceptive jelly
- Use of condoms with contraceptive foam
- Use of cervical cap with spermicide
- Contraceptive sponge

You should continue using birth control for 3 months after the last infusion of CPX-351.

# C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This study may or may not help you, but we hope the information from this study will help us develop better treatments for AML.

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# D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

Most of the medical care that you will receive in this project is considered routine care for your condition and would be recommended whether or not you join the project. Costs for routine care will be billed to you or your insurance carrier.

Activities / costs that are part of the project will not be billed to you or your insurance company. These are: the study questionnaires and the study-specific Nurse Teacher Education Program.

Some insurers will not pay for drugs, tests or hospitalization that are part of research, so check with your insurer before you join this project. If you have questions regarding costs, please contact Dr. Michaelis.

If you participate in this research, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

# D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

There is no payment for being in this project

# D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no. If you do not join this project, your research doctor can discuss other healthcare choices with you.

Your other choices may include:

- Joining a different research project
- The procedure or drug offered to you may also be available without being in any research project.
- Receiving no treatment

The research doctor can explain both the possible benefits and the risks of other options that are available to you.

# D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

If we learn any important new information about CPX-351 that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

When research data is collected and analyzed, there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research data. The results of your research data will be placed in your medical record.

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The results from the data we collect in this research study are the same quality as what you would receive as part of your health care. The data will be reviewed by a physician who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

# D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Dr. Michaelis, 414-805-6700.

# Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence. D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Michaelis at 414-805-6700.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

# E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

# E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); BloodCenter of Wisconsin (BCW); Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate-Froedtert Memorial Lutheran Hospital (FMLH), Inc.; Community Memorial Hospital (CMH) Menomonee Falls, Inc.; St. Joseph's Community Hospital (SJH) West Bend, Inc.; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

# The health information to be collected and used for this project is:

- Hospital/Medical Records
- Physician/Clinical Records

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- Lab and/or Pathology Reports
- Radiology Reports
- Biological Samples

# E2. Who will see the health information collected for this project?

The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

The research team may share your information with people who don't work at MCW/Froedtert Hospital because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

- The U.S. Department of Health & Human Services (DHHS)
- Jazz Pharmaceuticals and its affiliates, representatives, contractors, collaborators and licensees
- The Office for Human Research Protections (OHRP)
- Other government agencies in this or other countries
- The designated Data Safety Monitoring board and Institutional Review Board which is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner, and Privacy Boards and their related staff that have oversight responsibilities for this study.
- Personnel from the study site that provide study related treatment, procedures, or audits
- Those required by law

Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

# E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the research doctor about whether this could apply to you.

# E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this project.

# E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to

Laura Michaelis, MD Froedtert Hospital & the Medical College of Wisconsin Division of Hematology and Oncology, 9200 W Wisconsin Avenue Milwaukee, WI 53226

The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

# F1. FOR MORE INFORMATION ABOUT THE PROJECT

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 look up this project by referring to the ClinicalTrials.gov number (NCT03988205) or by asking the research team for a printed copy.

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# **CONSENT TO PARTICIPATE**

#### By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document, including Appendix 1. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

**IMPORTANT:** You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name please print	Subject's Signature	Date	
<b>Name of Witness (</b> if applicable) <i>please print</i> (for short form consent process, or consent of blind or illiterate subject)	Signature of Witness	Date	
Rationale for Use of Witness			
Subject has limited/no literacy	Sponsor requirement		
Subject has limited English	☐ Other		
proficiency			
Subject has limited/no vision			
* Name of person discussing/ obtaining consent please print	Signature of person discussing/obtaining consent	Date	

\* A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.

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Appendix 1: Example of Visit Schedule

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
	LABS/Vitals Visit with MD or APP Day 1: TREATMENT	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Physical Assessment by MD or APP TREATMENT	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Physical Assessment by MD or APP TREATMENT	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic
LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Visit with MD or APP; Quality of Life Surveys	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic		LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic
PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Visit with MD or APP	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	
LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Bone Marrow biopsy	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Visit with MD or APP	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic		LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic
PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic Visit with MD or APP	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	PHONE ASSESSMENT: Oncology Nurse	LABS/Vitals Assessment by Oncology Nurse in Day Hospital or Clinic	

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