UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: 1565GCC: Multicenter phase 1/2 study of combination therapy with the DNA methyltransferase inhibitor decitabine and the poly ADP ribose polymerase (PARP) inhibitor talazoparib (BMN 673) for untreated acute myeloid leukemia (AML) in adult patients unfit for cytotoxic chemotherapy or relapsed/refractory AML

Study No.: HP-00066370 **Version:** 3.1, Protocol v. 5; 17Apr2018

Principal Investigator: Maria Baer, M.D. Phone #: (410) 328-8708

Sponsor: Dr. Maria Baer, University of Maryland, Baltimore

Participant Name: _____ MR#_____

You are being invited to take part in this research study (or "study", for short) because you have acute myeloid leukemia (AML) that:

- did not respond to treatment ("refractory"), or
- responded to treatment but needs treatment again now ("relapsed"), or
- has not been treated yet, and your doctor thinks that you cannot be safely treated with standard chemotherapy or that your leukemia is not likely to respond to standard chemotherapy.

Please take your time to make your decision. It is important that you read and understand several general facts about research studies:

(a) Taking part in a research study is voluntary.

(b) You may or may not be helped by taking part in a research study, but knowledge gained from your taking part in the research study may help others;

(c) You may decide not to take part in a research study or, if you take part in a research study, you may decide to stop taking part at any time. If you decide not to take part in a research study or to stop taking part, this will not affect your medical care by your doctor and your healthcare team.

The purpose and nature of the study, possible benefits, risks and discomforts, other options, your rights as a participant, and other information about the study are discussed below. You are urged to discuss any questions that you have about this study with members of the study team. Take as much time as you need to discuss the study with your health care providers and with your family and friends. The decision to take part or not is yours.

If you decide to join the study, you will sign and date where indicated at the end of this form.

If you choose not to take part in this study, your healthcare at the University of Maryland, Baltimore will not be affected.

This research study is being funded by the Van Andel Research Institute-Stand Up To Cancer (VARI-SU2C) Epigenetics Dream Team. The study drug for this study is being provided by a pharmaceutical company called Pfizer, Inc.

PURPOSE OF STUDY

The purpose of this study is to find the best way to combine a new chemotherapy drug with one that is already in use to treat AML. The new experimental drug is called talazoparib (also known as BMN-673), and it is not approved by the Federal Drug Administration (FDA). The FDA is allowing the use of talazoparib for the purposes of this study.

Decitabine (also known as Dacogen), is being used off-label in this study. Off-label means that it has not been approved for AML by the FDA, but a doctor may still prescribe it if they believe it might help you. Decitabine is approved for older patients with AML in Europe. We want to find out the best dose of each drug to use when we treat patients with both drugs together.

Decitabine is given by injection into an intravenous (IV) line over one hour every day for five days. This treatment is repeated every 28 days.

Decitabine is a member of a class of drugs called DNA methyltransferase inhibitors. They are also sometimes called demethylating agents or hypomethylating agents. DNA methyltransferase inhibitors change expression of genes inside leukemia cells. Changing expression of the genes inside leukemia cells stops growth of leukemia cells. Decitabine is used to treat bone marrow diseases called myelodysplastic syndromes (MDS), as well as off label for AML.

Talazoparib is a pill that will be taken every day.

Talazoparib is a member of a class of drugs called poly ADP ribose polymerase inhibitors, or PARP inhibitors. PARP inhibitors stop cells from repairing damage to DNA caused by chemotherapy drugs, including DNA methyltransferase inhibitors. Lab work suggests that talazoparib will increase the effects of decitabine in leukemia cells.

We hope that treating patients with decitabine and talazoparib together will be more successful that treating patients with decitabine alone.

This study has two parts. The purpose of Part 1 is to find out the best doses of decitabine and talazoparib to use when they are given together to treat AML. Part 1 has 7 cohorts (groups). You will be told which cohort you will be assigned to if you join the study in Part 1. Also, in Part 1 we will study the effects of the drugs on leukemia cells obtained from blood samples before dosing and on Days 5 and 8. The purpose of part two is to see how well the drugs work together to treat AML. In Part 2 will study the effects of the drugs on leukemia cells obtained from blood samples before dosing and on Days 1, 5, 8, and 10 (Day 10 only if it is decided for Part 2).

Everyone in the study will be treated with decitabine and talazoparib.

Part one of the study will include as few as two people and as many as 36 people to find the best dose levels of the study drugs. Part One will begin enrolling first. Part Two of the study will not start until the Part One of the study is complete. You will be told which part of the study you may be enrolled in. Part Two of the study may include as few as 79 people and as many as 135 people. Part Two includes two separate arms. If you are enrolled in Part Two of the study, you will be assigned to one of the two arms below in order to test the success rate of the study drug dose and frequency found in Part One:

- Arm A will enroll adult patients with AML who are thought not to be likely to tolerate or respond to standard chemotherapy;
- Arm B will enroll adult patients with AML that has not responded to previous treatment or has come back after responding to previous treatment;

This is a multi-center study. Up to 171 people may take part in this study globally. As many as 36 people may take part in Part One locally. As many as 60 people may take part in this study in Part Two locally.

PROCEDURES

Screening

In order to make sure that you are eligible to take part in this study, the following procedures and tests will be done:

- Review of your medical history
- Physical exam, including vital signs, height and weight
- Bloodwork, including blood counts, chemistries and clotting tests (about 2 teaspoons)
- Electrocardiogram (EKG) and/or echocardiogram to measure the electrical activity of your heart (only if your doctor thinks it is needed for safety)
- A blood test to check for pregnancy, if you are a woman who can become pregnant (less than 1 teaspoon)
- Bone marrow aspirate and biopsy, including testing for chromosome changes and for gene changes frequently found in AML
- A swab of the inside your cheek to obtain cells to compare with your bone marrow cells

Treatment

If you are found to be able to enroll on the study after completing your screening tests, you will start taking the study drugs within one week. You will be assigned to a dose level of decitabine and of talazoparib. You will then begin dosing as described below.

This study is done in repeated cycles that are 28 days long. You will be given decitabine as an injection in a vein (IV) over one hour every day for five days, repeated every cycle if you are in cohorts 1-6 of Part 1. You will be given decitabine as an injection in a vein (IV) over one hour every day for ten days, repeated every cycle, if you are in cohort 7 of Part 1. You will be given decitabine as an injection in a vein (IV) over one hour every day for five or ten days (depending on the results of Part 1), repeated every cycle, if you are in Part 2. You will take talazoparib as a pill by mouth at the same time on every day

of every cycle. Missed morning doses may be taken later in the day. If a full day is missed, do not double up the next day.

The first cycle will start when you take your first doses of study drugs (Cycle 1 Day 1). Cycles may need to be delayed in order to allow your blood counts to recover or to allow side effects to get better. If you have low blood counts or other side effects, your doses of decitabine and talazoparib may be lowered in the next cycles.

In order to monitor your safety during dosing and your response to the drugs, the procedures listed below will be done:

Time Point	What will be Done

Cycle 1	• You will receive IV decitabine every day for five days (or 10 days if you are assigned to cohort 7 Part 1 or if it is decided for Part 2).
	• You will swallow a talazoparib pill every day at the same time for 28 days.
	• A study drug diary will be given to you on Day 1. You will use this to record when you take talazoparib.
	• Weekly medical history review
	• Weekly physical exam, including weight and vital signs
	• Weekly blood draws to check your health (about 2 teaspoons)
	• Two tablespoons of blood will be drawn at the following time points to answer study questions:
	  ○ Day 1 before dosing,
	  ○ Day 5, one hour after IV decitabine, and
	  ○ Day 8
	  ○ Day 10 (for participants on the 10-day decitabine regimen only)
	• Two teaspoons of blood will be drawn at the following time point to answer study questions:
	  ○ Day 29
	• Bone marrow aspirate and biopsy may be done around Day 29 if needed to assess your disease

Cycle 2	• You will receive IV decitabine every day for five days (or 10 days if you are assigned to cohort 7 Part 1 or if it is decided for Part 2). • You will swallow a talazoparib pill every day at the same time for 28 days. • A new study drug diary will be given to you on Day 1 to record when you take talazoparib. • Medical history review at least every two weeks • Physical exam, including weight and vital signs, at least every two weeks. • Blood draw to check your health (about 2 teaspoons) at least every two weeks.

	• Two teaspoons of blood will be drawn at the following time point to answer study questions: o Day 29 • Bone marrow aspirate and biopsy may be done around Day 29 if needed to assess your disease.
Subsequent Cycles	• You will receive IV decitabine every day for five days (or 10 days if you are assigned to cohort 7 Part 1 or if it is decided for Part 2). • You will swallow a talazoparib pill every day at the same time for 28 days. • A new study drug diary will be given to you on Day 1. • Medical history review on Day 1. • Physical exam, including weight and vital signs on Day 1. • Blood draw to check your health (about 2 teaspoons) on Day 1. • Two teaspoons of blood will be drawn for research at the following time point to answer study questions: o Day 29 • Bone marrow aspirate and biopsy may be done around Day 29 if needed to assess your disease
End of Study	• Medical history review • Physical exam • Blood draw to check your health (about 2 teaspoons) • You will return any unused study drug and empty bottles. • Your study drug diary will be collected.
Follow up	• You will be seen or contacted by phone or email at least every 6 months after you are off study for the rest of your life. Remember taking part in this study is research and you may withdraw at any time should you choose. Details about withdrawing from the study are listed later on in this document.

About 3 cups of blood may be taken from you in total during your first year on the study. Talk to your study doctor if you have any questions or concerns about the amount of blood being drawn in this study.

Tell the study doctor or staff about any medicines you are taking. This includes any over-the-counter drugs or herbal supplements which you bought from a store.

You may keep taking the study drugs until your study doctor determines that you should stop, due to side effects, progression of disease, or if you decide to stop taking part in the study.

Future Lab Studies

A portion of your bone marrow and blood samples will be stored frozen in a tissue bank. These samples will be used by the VARI-SU2C Epigenetics Dream Team for future leukemia research. Your samples will be stored for an unlimited time.

The use of your samples for future research will be based on whether your sample and data meet the scientific needs of the project. Future research may look at your genes, which are the units of inheritance that are passed down from generation to generation. Genes are responsible for many things about you such as eye color, hair color, blood type and hundreds of other traits. Future genetic testing may possibly include finding out the details of how your DNA is put together, or association studies that look at genes other than those connected to a specific disease. The gene materials may someday be injected into animals for research. We may share your samples and data with scientists at other institutions or research organizations.

Your samples may be used to make cell lines. Making cell lines is the process of using a single cell to make a lot of cells that all contain the same genes. It is possible that your tissue sample may be used to make a cell line that could be patented and licensed, or lead to new commercial products. If this happens, there is no plan to share any financial gain with you.

Using your samples for research is unlikely to help you. The research results may help people in the future. We hope that what we learn in future research studies will increase our knowledge of human health and that this information may lead to better prevention, diagnoses and treatments in the future.

You will not receive any payments for donating your samples and data into the research data bank.

Your samples will be stored in the data bank without any identifiers, but can be linked to your clinical data on the clinical trial.

Your research results will not be shared with you or with your health care provider.

You will not be contacted after the research study is over.

You can decide to change your mind later and withdraw your consent. To do so, please call Dr. Maria Baer at (410)-328-8708, or send your decision to withdraw in writing to:

Dr. Maria Baer
UMGCCC
22 South Greene Street S9D
Baltimore, Maryland 21201

If you would like your samples to be destroyed as well, you will need to specify as such in writing using the address listed above. Any data obtained before you withdraw your consent will still be used.

These procedures are being done for the research and will be paid for by the sponsor:

· Pregnancy testing

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this study, you must be responsible to:

- Make sure that you understand all information contained in this informed consent document.
- Make sure that your questions and concerns are answered by the study doctor and/or the study staff

- Come to your doctor's office or to the Infusion Center for all required study visits, and other visits requested by the study staff.
- Follow all instructions provided by the study doctor and study staff.
- Tell the study staff right away if you have any new side effects or your side effects get worse.
- Not start taking any new medications, including non-prescribed medicines, unless you have permission from your study doctor.
- Tell the study doctor and/or the study staff about any other medicines or supplements that you have taken (including vitamins, herbal or alternative remedies, or medicines that you buy over the counter).

POTENTIAL RISKS/DISCOMFORTS
Possible side effects of decitabine and of talazoparib in previous research studies are listed below.

Possible side effects of decitabine in previous research studies:
The following adverse events (side effects) were seen in earlier studies of decitabine and are categorized as Very Common (seen in 10% of patients or more) or Common (seen in between 1% and 10% of patients). Some of these affects may not have been due to decitabine:

Blood and lymphatic system
Very Common
- Low blood iron (anemia)
- Fever due to blood issues (febrile neutropenia)
- Low counts of white blood cells called neutrophils (neutropenia)
- Low blood platelets which can cause bleeding, bruising, and slow blood clotting (thrombocytopenia)

Common
- Low white blood cells (leukopenia)
- Low blood components (pancytopenia)
- Over production of blood platelets (thrombocythemia)
- Blood bilirubin increase

Heart
Common
- Chronic issues with pumping blood (congestive heart failure)
- Abnormally fast heart rate (tachycardia)

Ear
Common
- Ear pain

Digestive tract (Gastrointestinal)
Very Common
- Abdominal pain
- Constipation

- Diarrhea
- Nausea
- Indigestion (dyspepsia)
- Swelling and sores in the mouth (stomatitis)
- Vomiting

Common
- Upper abdominal pain
- Difficulty swallowing (dysphagia)
- Acid reflux (gastro-esophageal reflux disease)
- Oral pain
- Toothache

General and injection site
Very Common
- Physical weakness and low energy (asthenia)
- Chills
- Tiredness (fatigue)
- Fluid buildup and swelling in limbs (peripheral edema)
- Fever (pyrexia)

Common
- Chest pain
- Pain
- Swelling and inflammation of the mucus membranes (mucosal inflammation)
- Fluid buildup and swelling (edema)

Infections and infestations
Very Common
- Pneumonia
- Upper respiratory tract infection

Common
- Bacterial skin infection (cellulitis)
- Fungal infection in the mouth (oral candidiasis)
- Sinus infection (sinusitis)
- Staph infection in the blood (staphylococcal bacteremia)
- Tooth abscess
- Urinary tract infection

Injury, poisoning and procedural complications
Common
- Bruising (contusion)

Metabolism and nutrition
Very Common
- Low weight eating disorder (anorexia)

- Low blood potassium (hypokalemia)

Common
- Decreased appetite
- Dehydration
- High blood sugar (hyperglycemia)
- Low blood magnesium (hypomagnesemia)

Musculoskeletal and connective tissue
Very Common
- Joint pain (arthralgia)
- Back pain
- Pain in extremity

Common
- Bone pain
- Muscle spasms
- Muscular weakness
- Musculoskeletal pain
- Muscle pain (myalgia)

Nervous system
Very Common
- Dizziness
- Headache

Psychiatric
Very Common
- Difficulty sleeping (insomnia)

Common
- Anxiety
- Confused state
- Depression

Respiratory and chest area
Very Common
- Cough
- Difficulty breathing (dyspnea)
- Nose bleed (epistaxis)

Common
- Pain in the throat area (pharyngolaryngeal pain)
- Fluid buildup in chest tissues (pleural effusion)
- Sinus congestion
- Abnormal breathing sounds

Skin

Very Common

- Blood spots on the skin (petechiae)
- Rash

Common

- Dry skin
- Skin discoloration (ecchymosis)
- Red rash (erythema)
- Night sweats
- Itchy skin (pruritus)
- Skin lesion

Vascular

Very Common

- Low blood pressure (hypotension)

Common

- High blood pressure (hypertension)

The most common severe adverse events seen in previous studies were low blood neutrophils (neutropenia), low blood platelets (thrombocytopenia) and low blood iron (anemia). Blood toxicities and infections frequently caused drug dosing to be delayed and stopped. Eight patients died due to infection and/or bleeding that were considered at least possibly related to the drug. You will be watched very closely for blood based toxicities and infections so that you may be treated appropriately.

Possible side effects of talazoparib (commonly seen in previous studies):

- Low blood counts, including low platelet count (thrombocytopenia), low red blood cell count, low neutrophil counts (neutropenia), and low white blood cell count
- Anemia (low red blood cells)
- Fatigue (tiredness)
- Vomiting and nausea
- Low white blood cell count and infection
- Headache
- Hair loss (alopecia)
- Decreased appetite
- Diarrhea
- Abnormal/fast heart rhythm
- Blood lab abnormalities (low blood components such as hemoglobin, platelets, neutrophils, lymphocytes, leukocytes, and calcium, and /or increase in blood components such as glucose, alanine aminotransferase (ALT), aspartate aminotransferase (AST), and alkaline phosphatase. Please talk to the study doctor for more information regarding what these abnormalities could mean for you. You will be monitored throughout the study for safety.

If you are a woman who is able to become pregnant or a man who is able to father a child, there is a risk to your unborn children if you take part in this study.

For Women:
If you are a woman who is able to become pregnant, you will have a pregnancy test before beginning any study drug. You should use at least one effective birth control method (two are preferable when possible) if you are having sexual intercourse.

If you are pregnant, you cannot join this study because there may be risks to you and your unborn baby. Breastfeeding (nursing) mothers cannot join this study since it is not known whether the drugs in this study will be passed on to the baby in the mother's milk.

Tell one of the study doctors right away if:

- You are pregnant;
- You get pregnant; or
- You are breastfeeding.

For Men:
If your partner becomes pregnant, there could be harm to the unborn baby. You and your partner should use at least one effective birth control method (two are preferable when possible) if you are having sexual intercourse with a woman of childbearing potential.

If you become pregnant or think that you are pregnant or if your partner becomes pregnant or thinks that she is pregnant during the study, you must tell the study doctor right away. If you become pregnant, you will be taken off the study and will undergo the end of study procedures. If your partner becomes pregnant, you will remain on the study. If either you or your partner becomes pregnant during the study, you and/or your partner will be followed until the end of the pregnancy.

There may also be side effects, other than listed above that we cannot predict. Other drugs will be given to make side effects that occur less serious and less uncomfortable. Many side effects go away shortly after the drug or procedure is stopped, but in some cases, side effects can be serious, long-lasting, or permanent.

Biopsies: The removal of tumor tissue for research biopsies can cause pain, bruising and possibly infection at the biopsy site. Bleeding may also occur and in rare cases transfusions are needed to replace the blood lost. In very rare instances, such bleeding could require surgery or could even be fatal. The consent form provided by your study doctor for your biopsy will fully explain the risks of the procedure.

Privacy Risks
Since your personal health information will be used or disclosed to the sponsor, their representatives, and other authorized persons and entities, there is the risk of loss of confidentiality. Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet. Electronic data will be password-protected. Every effort will be made to protect your privacy.

There may be risks in this study which are not yet known.

POTENTIAL BENEFITS
You may or may not personally benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your part in this study. We hope the information learned from this research study will benefit other patients with relapsed or refractory AML in the future.

ALTERNATIVES TO PARTICIPATION
The following other procedures or treatments are available if you choose not to take part in this study:

- Getting treatment or care for your leukemia without being in a study.
- Taking part in a different research study.
- Getting supportive care, but no active treatment for your leukemia. Supportive care may include transfusions, antibiotics and medicine to lower your white blood cell count. Supportive care does not treat your leukemia, but tries to make you feel better; or
- Getting no treatment for your leukemia.

If you choose not to take part in this research study, your healthcare at the University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS
In this study, there are tests and procedures you will have that are standard of care (SOC) for treating your disease. SOC tests and procedures would be done whether or not you take part in the study. These SOC tests and procedures will be billed to you and/or your insurance company. Certain tests and procedures (e.g., infusions, physical exams, imaging, some lab tests) that are routine costs for clinical trials will also be billed to your insurance.

Your insurance company or government health care program may not want to pay for study related treatments and any problems that may come from the study. Before you decide to take part in this study, you may want to contact your insurance company so that you will know what is covered. Tests and procedures that are done only for the research study (not SOC or routine costs in clinical trials) will be paid for by the study sponsor.

Once received, your study coordinator will provide you with a copy of your completed insurance pre-authorization form. This document provides authorization details given to the University of Maryland Medical Center staff from your insurance carrier as to which study procedures your insurance carrier has agreed to cover

PAYMENT TO PARTICIPANTS
You will be given a parking voucher after completion of your research visits. You will not be paid to participate in the study

CONFIDENTIALITY AND ACCESS TO RECORDS
Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. It is a

requirement that your involvement in this research study is noted in your medical records. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified personally in any reports or publications resulting from this research study. Your personal information may be disclosed if required by law. Organizations that may request to inspect and/or copy your research or medical records for quality assurance and data analysis include groups such as:

- Representatives of University of Maryland, Baltimore (UMB)
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services and National Institutes of Health
- The Food and Drug Administration (FDA) and/or their representatives
- Pfizer, Inc and/or their representative(s).
- VARI-SU2C Epigenetics Dream Team and/or their partner(s).
- Any other individuals/organizations that analyze your health information in connection with this study as defined in the study protocol.

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to UMB by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this research study.

The confidentiality of your medical records will be maintained to the extent permitted by the applicable laws. If the results of the trial are published, your identity will remain confidential.

If information about your part in this research study is stored in a computer, we will take precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database. In addition, only personnel who are associated with the research study will have access to the study-specific records in the database.

Monitors, auditors, the IRB and the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access.

Data from this study will be shared with other scientists on the VARI-SU2C Epigenetics Dream team who are partnering in conducting this research. The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

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.

RIGHT TO WITHDRAW

Taking part in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part

in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator **Dr. Maria Baer at (410)328-8708**. Also, please send your request in writing to the investigator at the following address:

Marlene and Stewart Greenebaum Cancer Center
Clinical Research Office
22 South Greene Street
Baltimore, MD 21201-1595

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. Your decision to leave the study will have no effect on your future care by physicians or by this institution. Your decision to leave the study will have no adverse consequences (physical, social, economic, legal, or psychological)

If you withdraw from this study, information that has already been collected may not be removed from the study database. You will be asked whether the study doctor can collect information from your routine medical care. If you agree, this information will be handled the same as research data.

During the course of the study, any significant new findings that may affect your health, welfare, or willingness to stay in this study will be provided by your treating physician. In addition, if your treating physician believes that it is in your best interest for you to be withdrawn from this trial, she will do so right away, with or without your consent.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

CAN I BE REMOVED FROM THE RESEARCH?

The study doctors, physicians or sponsor may stop the study or remove you from the study without your consent at any time if:

- they judge that it is in your best interest to do so
- you experience an injury related to the study
- you need additional or different medication
- you do not comply with the study plan
- for various other administrative and medical reasons

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the IRB if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its

affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. **If you incur uninsured medical costs, they are your responsibility.** The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
(410) 706-5037

If you need help after hours, you may contact the Patient Assistance line at (410) 328-7609. Please reference the study doctor and study number on the first page of this consent form.

Signing this consent form indicates that you have read this consent form and understand the information in this consent form, that your questions have been answered to your satisfaction, and that you voluntarily agree to take part in this study. You will receive a copy of this signed consent form.

If you agree to take part in this study, please sign your name below.

_____ Patient's Signature	_____ Signature of Investigator or Designee Obtaining Consent
_____ Patient's Printed Name	_____ Printed Name of Investigator or Designee Obtaining Consent
_____	_____

Date	Date