Washington University in St. Louis

INFORMED CONSENT DOCUMENT – DONOR

Project Title: A Phase II Study of Cytokine Induced Memory-like NK Cell Adoptive Therapy after Haploidentical Donor Hematopoietic Cell Transplantation

Principal Investigator: Amanda Cashen, M.D.

Research Team Contact: Amanda Cashen M.D. – (314) 454-8323

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because your relative has a type of cancer called acute myeloid leukemia (AML) that can be treated in part with a transplant of some of your stem cells.

The purpose of this research study is to look at how long your relative's response to a routine stem cell transplant from you (a haploidentical donor) will last when s/he has also received treatment with your cytokine-induced memory-like natural killer (CIML NK) cells. A haploidentical stem cell transplant is a type of transplant that occurs when a person who needs a transplant cannot find a donor who exactly matches their tissue type (either among family members or through a matched unrelated donor). When no matched donor is available, half-matched related (haploidentical) donors may be used. A haploidentical donor is a first degree relative such as a sibling, child, or parent. NK cells are cells found in your bloodstream whose function is to fight infection and tumor cells. The type of NK cells that your relative will receive from you (CIML NK cells) are cells that will be activated to better fight leukemia cells after they have been collected from your body. The process to make these cells ready to fight the leukemia includes exposing them to protein signals called "cytokines" overnight. The reason for treating your relative with CIML NK cells after transplant is to enhance the graft versus leukemia effect, allowing the graft to be more successful and reduce the risk of graft rejection.

CIML NK cells are considered investigational, which means that they have not been approved by the U.S. Food and Drug Administration (FDA).

WHAT WILL HAPPEN DURING THIS STUDY?

All treatment will be given in either the outpatient or inpatient setting at Siteman Cancer Center. We feel it is important to remind you that any procedures regardless of whether they are tests you would have if you did not take part in the research or are research-related will require you to remain at the Siteman Cancer Center up to several hours to complete the necessary testing. There may also be a wide variability in the length of clinic visits due to the unique characteristics of your medical history and health condition as well as due to clinic factors such as physician availability, staffing shortages, and weather delays. This will also vary depending upon your needs at the visit as determined by your physician. It is important that you are able to be available to complete the procedures at each visit to ensure that your safety needs are met.

Before you begin study treatment:

You will need to have the following screening exams, tests, or procedures to find out if you can continue to be in the study. Most of these procedures are part of regular care and may be done even if you do not join the study but plan to donate cells to your relative as part of their routine care. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Physical exam, including taking of vital signs, reviewing your medical history, and talking about any symptoms or health problems you're having
- Blood tests (approximately 2½ tablespoons of blood) for the following reasons:
  - virology screen (to make sure you don't test positive for hepatitis or HIV)
  - HLA typing (human leukocyte antigen), which looks at how your tissue type matches your relative's type
  - baseline chimerism testing, which allows researchers to compare your blood cells with your relative's blood cells after s/he receives your cells
  - pregnancy test (if you are a woman who is able to become pregnant) (approximately 1 additional teaspoon of blood will be drawn, if necessary)
  - research studies, including testing which will study genes to study the differences in specific genes or small groups of genes in people who have AML when compared to people who do not have AML. Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes that determine things like our height or the color of our eyes. Some of these differences may make some people more or less likely to develop certain diseases or conditions or to have certain characteristics.

It is possible that after your medical history, tests, and procedures are reviewed, you will not be able to continue in this study. If this occurs, your study doctor will go over the reasons with you.

Otherwise, about a week before your relative is due to receive your stem cells, you will begin receive injections of filgrastim, a growth factor which helps in the collection of stem cells. The day before your relative is due to receive your stem cells, you will undergo leukapheresis, which involves placing two IVs into your arm which is connected to an apheresis machine or may involve placement of a central line, which is an IV that is inserted into a large vein in your chest under local anesthesia; the machine then takes the blood from the body, removes the stem cells, and returns the blood to your body. The stem cells will be infused the next day.

A second leukapheresis procedure may need to be done if not enough cells are collected after the first one. This will take place approximately the day after the first leukapheresis procedure. We will ask your permission before you undergo a second procedure. If you had a central line placed for the initial collection, this will remain in place until we can confirm that enough cells were collected. If a second collection is not required, then you will have the line removed. If you need to undergo a second collection, you will have another leukapheresis procedure and then the line will be removed.

Six days later, you will undergo another leukapheresis procedure, this time without receiving filgrastim beforehand. The cells taken from your body at this time will be processed in a non-standard way after they have been collected in order to activate them to be ready to fight the leukemia in your relative's bloodstream before they are infused. Some genetic research will be done on the cells collected during leukapheresis to see whether you and your relative are matched or mismatched for a certain gene and whether a match or mismatch affects how your relative responds to treatment.

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining blood and data from you. We would like to use this blood and data for studies going on right now as well as studies that are conducted in the future, including possible genetic research. These studies may provide additional information that will be helpful in understanding AML or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood and data you give up any property rights you may have in the blood and data.

Future research with your donated blood may include the study of genetic factors relating to AML. This future research may focus on one or more genes to study the differences in specific genes or small groups of genes in people who have AML when compared to people who do not have AML. Future research with your blood may also attempt to sequence large parts of your genome or even your entire genome. These types of sequencing provide detailed descriptions of your DNA and result in the creation of information that is as unique to you as your fingerprint.

We will share your blood and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your blood and data for future research you should contact the research team member identified at the top of this document. The blood and data will no longer be used for research purposes. However, if some research with your blood and data has already been completed, the information from that research may still be used. Also, if the blood and data has been shared with other researchers it might not be possible to withdraw the blood and data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood and data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My blood and data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 30 donor-recipient pairs (60 people total) will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for about 2 weeks. There may be a wide variability in the length of clinic visits due to the unique characteristics of your medical history as well as due to clinic factors such as physician availability, staffing shortages, and weather delays. This will also vary depending upon your needs at the visit as determined by your physician. Visits will range from 2 to 8 hours in length.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Risks of Leukapheresis

Less likely

- the medicine used to prevent blood from clotting in the machine can cause transient tingling or numbness around your mouth, feet or hands

Rare

- bleeding
- high or low blood pressure (high blood pressure is often associated with few or no symptoms; symptoms of low blood pressure include dizziness, fainting, blurred vision, nausea, and fatigue)
- muscle cramping
- chills and fever
- loss of red blood cells leading to anemia, which may cause tiredness and shortness of breath (a transfusion of packed red blood cells may be necessary)

- loss of platelets which may lead to easy bruising and bleeding (a transfusion of platelets may be necessary)
- if you have a central line placed, it is likely that you will experience bruising or discomfort at the insertion site, and there is a rare risk of lung collapse, deep vein thrombosis (serious blood clot), injury to an artery in your neck or chest, and abnormal heartbeat
- infection

It is possible that we may not collect enough cells. If that is the case, we may ask you if we can do a second collection. If you had a central line placed for the initial collection, this will remain in place until we can confirm that enough cells were collected. There is a minimal risk of infection and pain when leaving the central line in place.

Risks of Blood Draw

Possible side effects from a blood draw include fainting, feeling dizzy, pain, swelling, bruising, or bleeding where the needle is inserted. There is also a slight possibility of infection where the needle is inserted.

Risks of Testing for Reportable Diseases

If you decide to participate in this study, we will test you for HIV and hepatitis B and C. The results of the test could indicate that you have HIV or hepatitis B or C. If that happens, we will refer you to a doctor who specializes in treating HIV or hepatitis B and C. We will make every effort to keep your personal information confidential. However, we are required by law to report positive tests to the state of Missouri and/or local agencies. Becoming aware of a diagnosis of HIV or hepatitis B or C could have serious personal and/or social consequences, including difficulty obtaining health insurance or employment. For more information about the risks of HIV and hepatitis B and C testing, please talk to your study doctor.

Risks of Genetic Research

There may be information obtained from the genetic testing that indicates that you, or potentially a family member (since we inherit genes from our parents, and pass genes on to our children) are at risk for a particular disease or condition. For example, genetic sequencing may indicate that an individual is more prone to develop certain types of cancer or other types of neurological disease, (e.g. Alzheimer's).

If made available to persons or agencies outside of our research group, information about genetic test results could affect your employment or insurance. For instance, employers, insurers, or others may use this information when making decisions about you or your family members regarding employment, insurance, or other benefits.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Re-Identification from Genetic Sample

While the data developed for this study is being stored without traditional identifiers (stored only with coded ID numbers, no names), there may be ways of linking the genetic materials back to you. DNA does directly identify you, so it is possible that someone could compare information in our database with information from you in another database and be able to identify you.

Risks of Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because it will help researchers learn more about how to maximize treatment response to haploidentical stem cell transplants.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could participate in a different study or donate cells while not on a research study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

ImmunityBio, the National Institutes of Health (NIH), and The V Foundation are funding this research study. This means that Washington University is receiving payments from ImmunityBio, the NIH, and The V Foundation to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from ImmunityBio, the NIH, and The V Foundation for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 454-8304 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- ImmunityBio, manufacturer of ALT-803 (a drug that the transplant recipient will receive)
- The National Institutes of Health (NIH)
- The V Foundation
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- The Siteman Cancer Center Clinical Trials Office
- The Quality Assurance and Safety Monitoring Committee to monitor the conduct of the study

The research team will send study results to ImmunityBio. Information sent to ImmunityBio will not contain any identifiers. ImmunityBio will use this data to help evaluate the safety and efficacy of ALT-803 in this context. In the future, ImmunityBio may continue to use your health information that is collected as part of this study. For example, ImmunityBio may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study medication, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. ImmunityBio may also share information from the study with regulatory agencies in foreign countries.

If you receive Medicare benefits, are injured as part of your participation in this research study and medical treatment relating to this injury is paid by anyone other than you or your insurance company, that payer will need to collect personal information about you. This information includes your name, date of birth, gender, social security number, Medicare identification number and information related to this research study. The payer will report this information to the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, during your participation in the study and for as long as the payer is required by CMS to report this information. If you do not want to release your personal or treatment related information you have the right to refuse reimbursement by the payer for any research injury. The payer will not use this information for any other purpose.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your protected health information relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your health care records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

To help protect your confidentiality, we will make sure that your study information is kept secure. Medical records are considered confidential and records are kept in a secured area accessible to those involved in the conduct of the study. Information that is collected for the purpose of this study will be stored with your study number and initials on paper forms in locked cabinets and locked offices or in a password-protected database that only the study personnel will have access to which is also maintained in a locked office. A master list will be stored off-line (in a locked cabinet in a locked office) and available only to the Principal Investigator and his designee(s). Biologic specimens taken as part of this study will be labeled with initials, a linked code number, and date and time of collection and stored in a locked room accessible by WU badge. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

This consent form or similar documentation that you are participating in a research study will be included in your health care record. Anyone with access to your health care record, including your health insurance company will be able to see that you are participating in a research study.

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 this website at any time.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share

your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?
You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

If you decide to leave the study early, we will ask you to tell the study doctor so any risks can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

Will I receive new information about the study while participating?
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?
Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because staying in the study would be harmful, you need treatment that is not allowed while on the study, you fail to follow instructions, you become pregnant, you develop a major side effect, or the study is canceled.

WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Cashen at (314) 454-8323. If you experience a research-related injury, please contact Dr. Cashen as well; if this is after hours, you will be directed to the exchange number which will be covered by a resident or fellow on call. Please tell this person you are a research participant.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 11/26/25.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)

Washington University in St. Louis

INFORMED CONSENT DOCUMENT – RECIPIENT

Project Title: A Phase II Study of Cytokine Induced Memory-like NK Cell Adoptive Therapy after Haploidentical Donor Hematopoietic Cell Transplantation

Principal Investigator: Amanda Cashen, M.D.

Research Team Contact: Amanda Cashen, M.D. – (314) 454-8323

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have been diagnosed with acute myeloid leukemia (AML) that has not responded to treatment, has relapsed after initially responding to treatment, or has persistent abnormalities (known as minimal residual disease).

The purpose of this research study is to look at how long your response to a routine stem cell transplant from a haploidentical donor will last when you are also receiving treatment with cytokine-induced memory-like natural killer (CIML NK) cells. A haploidentical stem cell transplant is a type of transplant that occurs when a person who needs a transplant cannot find a donor who exactly matches their tissue type (either among family members or through a matched unrelated donor). When no matched donor is available, half-matched related (haploidentical) donors may be used. A haploidentical donor is a first degree relative such as a sibling, child, or parent. NK cells are cells found in your bloodstream whose function is to fight infection and tumor cells. The type of NK cells you will receive if you participate in this study (CIML NK cells) have been selected because they are activated to better fight leukemia cells. They will be processed after collection from your donor to make them ready to fight the leukemia before they are infused into your bloodstream. This process includes exposing them to protein signals called "cytokines" overnight. The reason for treating you with CIML NK cells after transplant is to enhance the graft versus leukemia effect, allowing the graft to be more successful and reduce the risk of graft rejection.

You will also receive a drug while on this study called ALT-803. ALT-803 is given to potentially help the NK cells fight the leukemia cells by supporting their survival and activating a more effective anti-leukemia immune response.

Both the CIML NK cells and ALT-803 are considered investigational, which means that they have not been approved by the U.S. Food and Drug Administration (FDA).

You will also receive some or all of the following drugs: fludarabine, cyclophosphamide, busulfan, tacrolimus, mesna, and mycophenolate mofetil. These drugs have not been approved by the FDA to be used the way they are being used in this study, which means they are considered investigational. However, they are approved to be used in other ways, and they are regularly used by physicians the way they are being used in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

All treatment will be given in the inpatient setting at Siteman Cancer Center. We feel it is important to remind you that any procedures regardless of whether they are tests you would have if you did not take part in the research or are research-related will require you to remain at the Siteman Cancer Center up to several hours to complete the necessary testing. There may also be a wide variability in the length of clinic visits due to the unique characteristics of your medical history and health condition as well as due to clinic factors such as physician availability, staffing shortages, and weather delays. This will also vary depending upon your needs at the visit as determined by your physician. It is important that you are able to be available to complete the procedures at each visit to ensure that your safety and treatment needs are met.

Before you begin study treatment:

You will need to have the following screening exams, tests, or procedures to find out if you can continue to be in the study. Most of these procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Physical exam, including taking of vital signs, reviewing your medical history, and talking about any symptoms or health problems you're having
- Blood tests (approximately 2 tablespoons of blood) for the following reasons:
  - to check your blood counts and organ function
  - virology screen (to make sure you don't test positive for hepatitis or HIV)
  - HLA typing (human leukocyte antigen), which looks at how your tissue type matches your donor's type
  - baseline chimerism testing, which allows researchers to compare your blood cells before you receive the transplant to your blood cells after the transplant
  - tests for donor specific antibodies
  - pregnancy test (if you are a woman who is able to become pregnant) (approximately 1 additional teaspoon of blood will be drawn, if necessary)
- Bone marrow aspirate and biopsy to check on the status of your disease, and at this time approximately ½ to 1 teaspoon of this bone marrow will also be used for research purposes; this is a procedure during which a few teaspoons of your bone marrow and a little of the tissue will be removed using a hollow needle
- Chest X-ray or CT (computerized tomography) scan of the chest if you haven't had one done in the last 90 days. A CT scan uses X-rays to create a picture of the bones and soft tissues in your body, and in some cases a contrast medium will be used and you must not eat or drink anything for 4 hours before the test (the doctor will tell you if this is the case). A "contrast medium" is a

liquid or solid that helps make a sharper image from the scan. Before the scan, you will need to remove all jewelry. During the scan, you will lie on your back on an X-ray table. A strap may be placed across your body to prevent movement so that the X-ray will be clear. The table will then slide into a large tunnel-shaped machine.

- Pulmonary function tests to look at how your lungs are functioning if these tests haven't been done in the last 90 days; these tests involve breathing into a sensor to help measure the amount of air that can be inhaled and exhaled as well as the speed with which it can be inhaled and exhaled
- Electrocardiogram (EKG) to look at how your heart is functioning if this test hasn't been done in the last 90 days; this test involves putting sticky pads on your skin while the electrical activity of the heart is recorded
- Echocardiogram or MUGA (multiple gated acquisition) scan to look at how your heart is functioning if either of these tests haven't been done in the last 90 days. An echocardiogram uses a transducer (an instrument that transmits high-frequency sound waves) placed on your ribs near your breastbone to create a moving picture of your heart, and a MUGA uses a low-level radioactive substance (tracer) to label your red blood cells, after which your heart is scanned by a camera which can "see" the labeled blood cells and produces a moving image of your beating heart.

It is possible that after your medical history, tests, and procedures are reviewed, you will not be able to continue in this study. If this occurs, your study doctor will go over the reasons with you.

Procedures throughout the study:
You will be admitted to the hospital. You will then undergo treatment with chemotherapy, with or without radiation, to prepare your body for the stem cell transplant. Your doctor will choose one of the following treatment combinations:

1. Five treatments with a drug called fludarabine, which is given intravenously over the course of 30 minutes on Days -6 through -2, and two treatments with a drug called cyclophosphamide, which is given intravenously over the course of 60 minutes on Days -6 and -5. You will also receive a drug called mesna, given intravenously, before and after the cyclophosphamide. Mesna is routinely given with cyclophosphamide to mitigate some of its potential side effects. On Day -1, you will receive a single dose of total body irradiation.

2. Three treatments with fludarabine, given intravenously over the course of 30 minutes on Days -6 through -4, and eight doses of total body radiation, given twice daily for four days.

3. Five treatments with fludarabine, given intravenously over the course of 30 minutes on Days -6 through -2 and four treatments of a drug called busulfan, which is given intravenously over the course of 3 hours on days -6 through -3.

On Day 0, you will receive your stem cell transplant. The stem cells are infused into your body through your central line.

On Days +3 and +4, you will receive two treatments with cyclophosphamide, given intravenously over the course of 2 hours. The purpose of the post-transplant cyclophosphamide is to reduce your risk of graft-versus-host disease (GVHD), which occurs when some of the cells from the donor attack the

recipient's tissues, resulting in mild, moderate, or even life-threatening side effects to the recipient's skin, stomach, intestines, and liver. You will also begin taking two other drugs on Day +5 as part of your routine care in an effort to prevent GVHD. Both of these drugs (tacrolimus and mycophenolate mofetil) may be given intravenously or taken orally. You will take mycophenolate mofetil through Day +35 and tacrolimus through Day +180.

On Day +7, you will have the CIML NK cells infused over 15 to 60 minutes. Your vital signs will be monitored every 15 minutes during the infusion, then every 30 minutes for one hour after the end of infusion; this is to watch for a reaction to the infusion so that appropriate treatment can be given if needed. One hour before and four hours after the CIML NK infusion, you will receive acetaminophen (Tylenol) and/or diphenhydramine (Benadryl) to help prevent a reaction to the cells.

About four hours after the CIML NK cell infusion, you will receive your first injection of ALT-803. You will receive a total of four injections, given every 3 weeks (one each on Days +7, +28, +49, and +70).

On Day +14, you will also begin receiving injections of filgrastim, which is a drug given to help your white blood cell count recover. You will continue to receive it as part of your routine until your white blood cell count is high enough.

You will be seen frequently through Day +100, generally daily throughout hospitalization and at least once every week after that. After Day +100, your doctor will decide how often your visits are and what tests to obtain for you based on your clinical situation. You will undergo the following tests and procedures as part of your participation on this study:

- Physical exam (daily beginning on Day -6 through Day +14, weekly through Day +42, then on Day +60, Day +100, Month 6, Month 9, and Month 12); beginning on Day 14, the study team will also assess you to see if you have any signs of GVHD
- Blood tests to check your counts, kidney function, and electrolytes (daily beginning on Day -6 until your white blood cell count has recovered, weekly through Day +42, then on Day +60, Day +100, Month 6, Month 9, and Month 12)
- Blood test to check your liver function (weekly beginning on Day -6 through Day +42 (and on Days +1 and +2), then on Day +60, Day +100, Month 6, Month 9, and Month 12)
- Blood test for chimerism testing (Day +28 and Day +100)
- Bone marrow aspirate and biopsy to check on the status of your disease (Day +28 and Day +100)

At several time points during your participation, you will have 14 teaspoons (a little over ¼ of a cup) of blood drawn for research purposes, including testing which will allow researchers to compare your blood cells before you receive the CIML NK cells to your blood cells afterwards, and some genetic research to see whether you and your family member are matched or mismatched for a certain gene and whether a match or mismatch affects how you respond to treatment. Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes that determine things like our height or the color of our eyes. Some of these differences may make some people more or less likely to develop certain diseases or conditions or to have certain characteristics. The days on which you will have blood drawn for research are:

- Screening

- Day +3 before the cyclophosphamide (12 teaspoons)
- Day +7 prior to the CIML NK cell infusion
- Day +10
- Day +14
- Day +21
- Day +28
- Day +35
- Day +42
- Day +60
- Day +70
- Day +84
- Day +100
- Month 6
- Month 9
- Month 12
- Month 18
- Month 24
- At the discretion of your doctor, additional samples may be collected depending on the status of your disease

You will also have bone marrow collected for research purposes on the following days:

- Screening (as described above)
- Day +14
- Day +28 (at the time of routine bone marrow collection)
- Day +100
- At the time of any routine bone marrow collection

After your 12-month visit, you will begin long-term follow-up. This will consist of either an annual physical exam or a telephone call from a member of the study team to check on your health status.

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining blood, bone marrow, and data from you. We would like to use this blood, bone marrow, and data for studies going on right now as well as studies that are conducted in the future, including possible genetic research. These studies may provide additional information that will be helpful in understanding AML or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood, bone marrow, and data you give up any property rights you may have in the blood, bone marrow, and data.

Future research with your donated blood and bone marrow may include the study of genetic factors relating to AML. This future research may focus on one or more genes to study the differences in

specific genes or small groups of genes in people who have AML when compared to people who do not have AML. Future research with your blood and bone marrow may also attempt to sequence large parts of your genome or even your entire genome. These types of sequencing provide detailed descriptions of your DNA and result in the creation of information that is as unique to you as your fingerprint.

We will share your blood, bone marrow, and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your blood, bone marrow, and data for future research you should contact the research team member identified at the top of this document. The blood, bone marrow, and data will no longer be used for research purposes. However, if some research with your blood, bone marrow, and data has already been completed, the information from that research may still be used. Also, if the blood, bone marrow, and data has been shared with other researchers it might not be possible to withdraw the blood, bone marrow, and data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood, bone marrow, and data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

My blood, bone marrow, and data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes **_____ No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 30 donor-recipient pairs (60 people total) will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 4 years (including follow-up), although only the first 4 months will require intensive participation. The length of time for each visit will vary due to the unique characteristics of your medical history and health condition as well as due to clinic factors such as physician availability, staffing shortages, and weather delays. This will also vary depending upon your needs at the visit as determined by your physician. During the transplant period, you will be admitted the hospital (inpatient). After transplant, you will remain admitted until your physician feels that you are able to safely return home. Your post-transplant visits may vary from 2 to 8 hours in length depending on what procedures are being performed at each individual visit.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Risks of CIML NK Cell Infusion

Likely

- Fever
- Chills
- Headache
- Rash
- Muscle pain
- Vomiting
- Diarrhea

Rare

- Capillary leak syndrome (CLS) in combination with ALT-803. CLS is a combination of symptoms that include fluid accumulating in tissues that may result in swelling, pulmonary congestion, shortness of breath, pleural effusions (fluid in the layers of tissue just outside the lungs), and ascites (fluid in the abdominal cavity, causing abdominal swelling). In serious cases this may result in the respiratory failure and systemic shock (a serious condition in which the organs and tissues of the body are not receiving an adequate flow of blood), and death.

Risks of ALT-803

Likely

- Fever and chills
- Flu-like symptoms (such as fever, chills, sweats, shaking, headache, stiffness, aching muscles and joints)
- Hypoalbuminemia- Very low levels of albumin in the blood. Albumin is a blood protein that is part of the blood plasma.
- Diarrhea
- Nausea and vomiting
- Hypertension- high blood pressure
- Headache
- Fatigue
- Cough
- Abdominal pain
- Back pain
- Decreased Lymphocyte Count- Lymphocytes are a type of white blood cell and a decreased count can by a sign of possible infection or inflammation in the body
- Anemia- This is due to a drop in the number of red blood cells made by your bone marrow,

- Lack of or loss of appetite
- Injection Site Reaction- Typically includes redness, firmness or swelling, and pain or itching
- Itching sensation of the skin
- Urinary tract infection
- Constipation
- Shortness of breath
- Dizziness
- Leg swelling
- Low blood sodium level
- Low blood potassium level
- Low blood pressure
- Dehydration
- Elevated liver enzymes in the blood (could indicate liver damage)
- Insomnia

Less likely

- Development of an immune response against ALT-803. This could decrease the effects of the drug. Severe allergic reaction
- Neutropenia- a low number of neutrophils, a type of white blood cell
- Febrile Neutropenia- a fever during a period of neutropenia

Rare

- Atrial Fibrillation- an irregular heartbeat
- Bleeding

Risks of Fludarabine

Likely

- Infection, especially when white blood cell count is low
- Vomiting
- Loss of appetite
- Tiredness
- Fever
- Pain
- Bruising or bleeding
- Cough
- Increased risk of unusual infections lasting more than 6 months

Less likely

- Anemia and kidney problems which may cause tiredness, bruising, or swelling
- Nausea
- Chills
- Feeling of "pins and needles" in arms and legs
- Damage to organs which may cause tiredness, changes in thinking, or shortness of breath
- Confusion

Rare and serious

- Kidney damage which may require dialysis

Risks of Cyclophosphamide

Likely

- Hair loss
- Skin changes
- Rash
- Change in nails
- Nausea
- Vomiting
- Diarrhea
- Loss of appetite
- Pain in belly
- Sores in mouth
- Infection, especially when white blood cell count is low
- Absence of menstrual period which may decrease the ability to have children
- Blood in urine

Less likely

- Damage to the bone marrow (irreversible), which may cause infection or bleeding and may require transfusions
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, and swelling of the face or throat
- Loss or absence of sperm which may lead to an inability to father children
- Stuffy nose
- Scarring of the lungs which may cause shortness of breath
- Fluid around the heart

Rare and serious

- Severe skin rash with blisters and peeling which can involve mouth and other parts of the body
- Damage to the heart or heart failure which may cause shortness of breath, swelling of ankles, cough, or tiredness
- A new cancer including cancer of the bone marrow (leukemia) caused by chemotherapy
- Swelling of the body including the brain which may cause dizziness or confusion

Risks of Mesna

Likely

- Nausea or vomiting
- Tiredness
- Headache
- Pain in the arms or legs
- Unpleasant taste

Less likely

- Low blood pressure which may cause you to feel faint

Risks of Busulfan

Likely

- Anemia which may require blood transfusions
- Infection, especially when white blood cell count is low
- Bruising, bleeding
- Diarrhea, nausea, vomiting, loss of appetite
- Sores in mouth which may cause difficulty swallowing
- Belly pain
- Headache
- Difficulty sleeping
- Worry
- Fever

Less Likely

- Seizure
- Internal bleeding which may cause coughing up blood
- Damage to or scarring of the lungs
- Damage to the liver
- Menopause

Rare and Serious

- Fluid around heart
- Cancer of bone marrow caused by chemotherapy

Risks of Total Body Irradiation

Likely

- Diarrhea
- Nausea
- Stomach cramps
- Vomiting
- Painful swelling of the salivary glands
- Short-term hair loss
- Anemia
- Infection
- Bleeding
- Cataracts, where the lens of the eye becomes opaque (resulting in blurred vision)
- Sterility (inability to have children)
- Slow growth
- Hormone problems (thyroid disease or diabetes)
- Mouth Sores

Less likely

- Lung inflammation
- Pneumonia (lung infection)
- Redness of the skin
- Serious liver problems, which could cause jaundice (yellow eyes and skin), abdominal pain and swelling, swelling in the legs and ankles, itching, dark urine, nausea, or vomiting

Rare

- Risk of developing other cancers in the future
- Difficulty swallowing
- Back problems
- Kidney problems, which could cause nausea and vomiting, passing only small amounts of urine, swelling in the legs and ankles, fatigue, loss of appetite, and high blood pressure
- Learning problems

Risks of Stem Cell Transplant

Likely

The side effects of stem cell transplant may include GVHD, as well as the development of low blood counts. If you develop GVHD, you will be treated with steroids and other standard of care treatments for GVHD if necessary. If you develop low blood counts, you will be supported with blood transfusions, antibiotics, and filgrastim (a growth factor for white blood cells) as necessary.

Altered immune function is common after stem cell transplantation. You therefore have a significant risk of getting a variety of infections, including bacterial or fungal infections. Antibiotic or antifungal therapy will be given as medically indicated.

Rare

Rarely (5-10%) the stem cells transplanted fail to fully engraft the recipient. Patients who are not complete or are mixed chimeras (not all blood and bone marrow cells are replaced with donor cells) are at risk of bone marrow failure (the bone marrow is unable to produce enough blood cells) after the infusion of stem cells. The bone marrow failure may be lethal if the bone marrow does not recover afterwards. If you develop bone marrow failure, you will be supported with blood transfusions, antibiotics and growth factors until additional stem cells can be infused from the original donor.

Risks of Tacrolimus

Likely

- Anemia, which may cause tiredness or may require blood transfusions
- Constipation
- Diarrhea
- Nausea
- Vomiting
- Bruising or bleeding
- Diabetes
- Abnormal body movement

- Feeling of "pins and needles" in the arms or legs
- Headache
- Dizziness
- Difficulty sleeping
- Kidney damage which may cause swelling and may require dialysis
- Hair loss
- Itching, rash
- High blood pressure which may cause dizziness or blurred vision
- Swelling of the body
- Fever
- Infection, especially when white blood cell count is low

Less likely

- Damage to organs which may cause changes in thinking, confusion, memory loss, or shortness of breath
- Allergic reaction which may cause, rash, low blood pressure, wheezing, shortness of breath, or swelling of the face or throat
- Change in the heart rhythm, abnormal heartbeat, or heart stops beating
- Heart attack or failure which may cause chest pain, swelling of the ankles, and tiredness
- A tear or hole in the stomach which may cause belly pain or require surgery
- A new cancer resulting from treatment of an earlier cancer
- Brain damage, which may cause headache, seizure, or blindness

Risks of Mycophenolate Mofetil

Mycophenolate must not be taken by women who are pregnant or who may become pregnant. There is a higher risk that mycophenolate will cause miscarriage (loss of the pregnancy) during the first 3 months of pregnancy or will cause the baby to be born with birth defects (problems that are present at birth).

Mycophenolate weakens the body's immune system and may decrease your ability to fight infection. Wash your hands often and avoid people who are sick while you are taking this medication. If you experience any symptoms of infection, call your doctor immediately.

Mycophenolate may increase the risk that you will develop progressive multifocal leukoencephalopathy (PML; a rare infection of the brain that cannot be treated, prevented, or cured and that usually causes death or severe disability). Tell your doctor if you have or have ever had PML, or another condition that affects your immune system such as human immunodeficiency virus (HIV); acquired immunodeficiency syndrome (AIDS); sarcoidosis (a condition that causes swelling in the lungs and sometimes in other parts of the body); leukemia (cancer that causes too many blood cells to be produced and released into the bloodstream); or lymphoma (a type of cancer that develops in the lymph system). If you experience any of the following symptoms, call your doctor immediately: weakness on one side of the body or in the legs; difficulty or inability to control your muscles; confusion or difficulty thinking clearly; unsteadiness; memory loss; difficulty speaking or understanding what others say; or a lack of interest or concern for usual activities or things you usually care about.

Mycophenolate may increase your risk of developing certain types of cancer, including lymphoma and

skin cancer. Tell your doctor if you or anyone in your family has or has ever had skin cancer. Avoid unnecessary or prolonged exposure to real and artificial sunlight (tanning beds, sunlamps) and light therapy and wear protective clothing, sunglasses, and sunscreen (with a SPF factor of 30 or above). This will help to decrease your risk of developing skin cancer. Call your doctor if you experience any of the following symptoms: pain or swelling in the neck, groin, or armpits; a new skin sore or bump; a change in the size or color of a mole; a brown or black skin lesion (sore) with uneven edges or one part of the lesion that does not look like the other; skin changes; sores that do not heal; unexplained fever; tiredness that does not go away; or weight loss.

The common side effects associated with mycophenolate mofetil include:

- Diarrhea
- Leukopenia (low white blood cell count), which increases your risk of infection
- Sepsis (blood infection)
- Vomiting
- Opportunistic infections (infections that occur because your immune system is compromised)
- Pain
- Abdominal pain
- Swelling of the lower legs, ankles, and feet
- High blood pressure

Risks of Central Line Placement

It is likely that you will experience bruising or discomfort at the insertion site, and there is a rare risk of lung collapse, deep vein thrombosis (serious blood clot), injury to an artery in your neck or chest, and abnormal heartbeat.

Risks of Blood Draw

Possible side effects from a blood draw include fainting, feeling dizzy, pain, swelling, bruising, or bleeding where the needle is inserted. There is also a slight possibility of infection where the needle is inserted.

Risks of Testing for Reportable Diseases

If you decide to participate in this study, we will test you for HIV and hepatitis B and C. The results of the test could indicate that you have HIV or hepatitis B or C. If that happens, we will refer you to a doctor who specializes in treating HIV or hepatitis B and C. We will make every effort to keep your personal information confidential. However, we are required by law to report positive tests to the state of Missouri and/or local agencies. Becoming aware of a diagnosis of HIV or hepatitis B or C could have serious personal and/or social consequences, including difficulty obtaining health insurance or employment. For more information about the risks of HIV and hepatitis B and C testing, please talk to your study doctor.

Risks of Bone Marrow Aspirate and Biopsy

It is likely that you will experience discomfort or pain, redness, swelling, and bruising at the site of the needle insertion. It is less likely that you will experience bleeding from the site of the needle insertion. There is a rare chance (approximately less than 1/100) of developing a significant infection or bleeding

from this procedure. An allergic reaction to the anesthetic may occur. A scar may form at the site of needle entry.

Risks of CT Scan or Chest X-Ray

If you are scheduled for a CT with contrast, the dye that is injected into a vein for the scan is usually well tolerated. Some people feel dizzy, queasy, or get a headache when given the dye or notice a cold feeling near the injection site. There is a rare chance of having an allergic reaction to the dye that very rarely can be serious or life threatening. You must tell your doctor if you have had bad reactions to dyes before. There is also a rare chance that a CT scan may cause a malfunction of worn or implanted medical devices. If you have electronic medical devices implanted such as a pacemaker or a drug pump, please make sure you tell your study doctors and research staff. The CT scan may cause a malfunction of electronic medical devices.

Risks of EKG

The risks can include skin irritation and a rash due to wearing and the removal of the electrodes. The electrodes only detect electrical impulses produced by the heart. No electricity passes through the body from the machine, and there is no danger of getting an electrical shock.

Risks of Echocardiogram

You should feel no pain with this test. You may experience discomfort from lying quietly for a long period of time.

Risks of MUGA Scan

Allergic reactions to the tracer are rare. Most of the tracer will be eliminated from your body within a day. You may have some pain or swelling where the tracer is injected into your vein.

Risks of Radiation Exposure

In addition to radiation therapy, this research study involves radiation exposure from a single MUGA scan (if you have one instead of an echocardiogram) and a single CT scan or chest x-ray if you haven't had one within the last 90 days. This radiation exposure is a small fraction of the exposure you may receive as part of the radiation therapy and therefore the additional risk, if any, is too small to be measured. If you would like more information about radiation exposure, please see the "Radiation Fact Sheet" located at http://hrpo.wustl.edu or ask the study staff for a copy.

Risks for Women Capable of Becoming Pregnant

If you are a woman capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Risks of Radiation Exposure in Women Capable of Becoming Pregnant

You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before exposing you to research-related radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

Risks of Sexually Active Males

If you are a sexually active male it is important that your partner not become pregnant during your participation in this study. There may be unknown risks to the unborn child or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you believe or know that your partner has become pregnant during your participation in this study, please contact the research team member identified at the top of this document as soon as possible.

Risks of Genetic Research

There may be information obtained from the genetic testing that indicates that you, or potentially a family member (since we inherit genes from our parents, and pass genes on to our children) are at risk for a particular disease or condition. For example, genetic sequencing may indicate that an individual is more prone to develop certain types of cancer or other types of neurological disease, (e.g. Alzheimer's).

If made available to persons or agencies outside of our research group, information about genetic test results could affect your employment or insurance. For instance, employers, insurers, or others may use this information when making decisions about you or your family members regarding employment, insurance, or other benefits.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Re-Identification from Genetic Sample

While the data developed for this study is being stored without traditional identifiers (stored only with coded ID numbers, no names), there may be ways of linking the genetic materials back to you. DNA does directly identify you, so it is possible that someone could compare information in our database with information from you in another database and be able to identify you.

Risks of Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because it will help researchers learn more about how to maximize treatment response to haploidentical stem cell transplants.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could:

- Get treatment or care for your cancer without being in a study;
- Take part in another research study;
- Get no treatment;
- Get comfort care, also called palliative care, which helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer without treating the cancer directly.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.

If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

ImmunityBio, Inc, the National Institutes of Health (NIH), and The V Foundation are funding this research study. This means that Washington University is receiving payments from ImmunityBio, Inc, the NIH, and The V Foundation to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from ImmunityBio, Inc, the NIH, and The V Foundation for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 454-8304 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- ImmunityBio, Inc, manufacturer of ALT-803
- The National Institutes of Health (NIH)
- The V Foundation
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- The Siteman Cancer Center Clinical Trials Office
- The Quality Assurance and Safety Monitoring Committee to monitor the conduct of the study

The research team will send study results to ImmunityBio, Inc. Information sent to ImmunityBio, Inc will not contain any identifiers. ImmunityBio, Inc will use this data to help evaluate the safety and efficacy of ALT-803 in this context. In the future, mmunityBio, Inc may continue to use your health information that is collected as part of this study. For example, mmunityBio, Inc may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study medication, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. ImmunityBio, Incs may also share information from the study with regulatory agencies in foreign countries.

If you receive Medicare benefits, are injured as part of your participation in this research study and medical treatment relating to this injury is paid by anyone other than you or your insurance company, that payer will need to collect personal information about you. This information includes your name, date of birth, gender, social security number, Medicare identification number and information related to this research study. The payer will report this information to the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, during your participation in the study and for as long as the payer is required by CMS to report this information. If you do not want to release your personal or treatment related information you have the right to refuse reimbursement by the payer for any research injury. The payer will not use this information for any other purpose.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your

protected health information relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your health care records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

To help protect your confidentiality, we will make sure that your study information is kept secure. Medical records are considered confidential and records are kept in a secured area accessible to those involved in the conduct of the study. Information that is collected for the purpose of this study will be stored with your study number and initials on paper forms in locked cabinets and locked offices or in a password-protected database that only the study personnel will have access to which is also maintained in a locked office. A master list will be stored off-line (in a locked cabinet in a locked office) and available only to the Principal Investigator and his designee(s). Biologic specimens taken as part of this study will be labeled with initials, a linked code number, and date and time of collection and stored in a locked room accessible by WU badge. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

This consent form or similar documentation that you are participating in a research study will be included in your health care record. Anyone with access to your health care record, including your health insurance company will be able to see that you are participating in a research study.

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 this website at any time.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?
You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

If you decide to leave the study early, we will ask you to tell the study doctor so any risks can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

Will I receive new information about the study while participating?
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?
Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because staying in the study would be harmful, you need treatment that is not allowed while on the study, you fail to follow instructions, you become pregnant, you develop a major side effect, or the study is canceled.

WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Cashen at (314) 454-8323. If you experience a research-related injury, please contact Dr. Cashen as well; if this is after hours, you will be directed to the exchange number which will be covered by a resident or fellow on call. Please tell this person you are a research participant.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 11/26/25.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)