Participant Informed Consent for Clinical Research

Study title for participants: A Modified Dose of Rabbit Anti-thymocyte Globulin (rATG) in Children and Adults Receiving Treatment to Help Prepare Their Bodies for a Bone Marrow Transplant

Official study title for internet search on http://www.ClinicalTrials.gov: Phase 2 Study of Personalized r-ATG Dosing to Improve Survival Through Enhanced Immune Reconstitution in Pediatric and Adult Patients Undergoing ex-vivo CD34-Selected Allogeneic-HCT (PRAISE-IR)

Lead Researcher: Kevin Curran, MD (212-639-5836)

If you are the legally authorized representative (LAR) of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to the study participant.

Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

You are being asked to take part because you have a type of acute leukemia (cancer of the blood and bone marrow) or myelodysplastic syndrome (MDS—a type of cancer in which the bone marrow is unable to produce normal levels of certain blood cells). You are going to receive an allogeneic hematopoietic cell transplant (allo-HCT) as part of the standard treatment for your disease. During the allo-HCT, you will receive healthy blood-forming cells (stem cells) from a donor to replace the diseased or damaged cells in your bone marrow.

Before your transplant, you will receive one of two combinations of chemotherapy and possibly total body irradiation (TBI—which involves treating your whole body with radiation). In addition, you will receive a drug called rabbit anti-thymocyte globulin (rATG). These combinations are called conditioning regimens and are standard treatment for your disease. These regimens help make room for the donated cells to grow, prevent your body from rejecting donated cells, and kill any cancer cells that are in your body.

rATG targets and deactivates white blood cells called T cells. T cells normally help to protect against infections from harmful bacteria and viruses, but they can also attack the new stem cells you receive from a donor. Researchers think that adjusting (modifying) the dose of rATG based on a patient's weight and white blood cell count may help the patient's immune system recover sooner, and prevent transplant-related side effects. This modified dose of rATG is called personalized rATG (P-rATG).

We are doing this study to see if conditioning regimens that include P-rATG help the immune system recover sooner and decrease the chances of transplant-related side effects.

The conditioning regimens used in this study are the standard regimens used at Memorial Sloan Kettering Cancer Center (MSK) for allo-HCT. The only part of this study that isn't standard is modifying the dose of rATG to create a P-rATG.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach to my allo-HCT?

People who are not in a research study are usually treated with the two standard conditioning regimens that are being used in this study. People receive these regimens before their allo-HCT. People who are not in a research study usually receive a standard dose of rATG and do not receive a P-rATG based on their weight and white blood cell count.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available
- You may choose not to be treated for cancer
- You may choose not to be treated for cancer, but to receive comfort care to help relieve your symptoms

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will receive one of two standard conditioning regimens to help prepare your body for your transplant. You will find more detailed information about these regimens later in this consent form. With either regimen, you will receive the P-rATG 12 days before your transplant.

You will be admitted to the hospital the day before you start the chemotherapy that is part of your regimen. Both conditioning regimens last 11 days. You will not receive any chemotherapy on the day before your transplant.

The allo-HCT you will receive is part of your standard care and not part of this study. The allo-HCT will be T-cell depleted, which means that T cells will be removed to reduce or prevent transplant-related side effects. This T-cell removal process is called CD34-positive selection. This is a standard type of transplant at MSK. You will find more information about the allo-HCT in a separate consent form you must read and sign before having the procedure.

Starting 7 days after your transplant, you will receive a standard medication called granulocyte-colony stimulating factor (G-CSF), which helps your bone marrow make more white blood cells. You will receive G-CSF until your blood counts recover.

You will have follow-up evaluations while you are in the hospital after the transplant procedure. After you are released from the hospital, you will return to the clinic so the study doctor and study team can check your health and see if you are having any side effects from the conditioning regimen and transplant. The study doctor and study team will continue to follow your health for at least 1 year after your transplant. This follow-up will be part of your standard care.

After your transplant if you agree to take part in the optional quality of life study, you will complete study questionnaires at the clinic monthly for 1 year, and then every 3 months for 2 years. These questionnaires ask about your qualify of life, your symptoms, and how your disease is affecting your daily life. After you complete the 3-year questionnaire, your participation in this study will be complete.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach at shrinking or stabilizing your cancer.

If you choose to take part in this study, there is a risk that you could have side effects from the study approach.

Some of the most common side effects of the conditioning regimens that the study doctors know about are:

- Fever
- Chills
- Decreased number of white bloods cells called neutrophils (neutropenia), which increases the risk of infection
- Decreased number of platelets (blood cells that help with clotting), which increases the risk of bleeding and/or bruising
- Headache

There may be some risks that the study doctors do not yet know about.

Benefits

The conditioning regimens used in this study are standard regimens patients receive before an allo-HCT. It's possible that receiving a conditioning regimen that includes P-rATG will help your immune system recover sooner and/or decrease your chances of transplant-related side effects. However, we do not know if a conditioning regimen that includes P-rATG will be more effective than one that includes rATG at a dose that has not been specially modified for you. This study may help the study doctors learn things that may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible. It's important that you stop safely.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- For women who are able to have children: You become pregnant while you are in the study
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), US Food and Drug Administration (FDA), or the study sponsor, MSK. The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

The purpose of this study is to see if conditioning regimens that include personalized rabbit ATG (P-rATG) help the immune system recover sooner and decrease the chances of transplant-related side effects. Participants in this study will be children and adults who have acute leukemia or myelodysplastic syndrome (MDS), and they will receive a standard conditioning regimen to prepare the body for an allogeneic hematopoietic cell transplant (allo-HCT). The conditioning regimen will include r-ATG, one of two combinations of chemotherapy, and possibly total body irradiation (TBI).

r-ATG is made of proteins from rabbits that target and deactivate white blood cells called T cells. T cells normally help to protect against infections from harmful bacteria and viruses, but they can also attack the new stem cells you receive from a donor. Researchers think that modifying the dose of rATG based on your weight and white blood cell count may help prevent the donated cells from being rejected, help your immune system recover sooner, and prevent transplant-related side effects. This modified dose of rATG is called personalized rATG (P-rATG).

The two chemotherapy combinations used in this study include 1) thiotepa and cyclophosphamide and 2) busulfan, melphalan, and fludarabine. These drugs kill cancer cells in the body, making room in the bone marrow for the donated cells to grow and reducing the chance of your body rejecting donated cells. Participants in this study who receive thiotepa and cyclophosphamide will also have TBI, which is radiation therapy that damages your cancer cells and makes it hard for them to reproduce.

The FDA has approved all drugs used in this study. The conditioning regimens used in this study are the standard regimens used at MSK for allo-HCT. The only part of this study that isn't standard is modifying the dose of rATG to create a P-rATG.

About 56 people will take part in this study at MSK.

What are the study groups?

This study has two study groups. The study doctor will decide which group you are in, and his decision will depend on your medical history, type of leukemia, and current health.

- **Conditioning Regimen A:** Participants will receive P-rATG with total body irradiation, thiotepa, and cyclophosphamide (TBI/thio/cy)
- **Conditioning Regimen B:** Participants will receive P-rATG with busulfan, melphalan, and fludarabine (bu/mel/flu)

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in the study. This first part of the study is called screening. Most of the screening exams, tests, and procedures are part of the usual care that you would have if you were not in a study.

The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

Procedures that are being done for research purposes include:

- Optional Questionnaire that asks about your quality of life, your symptoms, and how your disease is affecting your daily life. It will take about 20 minutes to complete this questionnaire, which will be on paper or electronic.

During the study:

You will be treated with 1 of the 2 condition regimens described below. With either of these regimens, you be admitted to the hospital the day before you start chemotherapy.

Conditioning Regimens A and B:
The day of your transplant procedure is Day 0. The allo-HCT you will receive is part of your standard care and not part of this study. The allo-HCT will be T-cell depleted, which means that T cells will be removed to reduce or prevent transplant-related side effects. You will find more information about the allo-HCT in a separate consent form you must read and sign before having the procedure.

Twelve days before your transplant, you will receive P-rATG for 2-3 days (Days -12 to -10 or -12 to -11). You will receive P-rATG as an intravenous (IV) infusion through a needle placed in a vein in your arm. Each infusion will last 6-12 hours. You may be in the hospital for up to 45 days, or longer if you have serious side effects.

Conditioning Regimen A only: On Days -9 to -6, you will have TBI. Each radiation therapy session will take about 20 minutes.

On Days -5 and -4, you will receive thiotepa by IV infusion. Each infusion will last about 3 hours. On Days -3 and -2, you will receive cyclophosphamide by IV infusion. Each infusion will last about 1 hour.

You will rest the day before your transplant (Day -1), and you will not receive any treatment on this day.

Starting 7 days after your transplant, you will receive a standard medication called granulocyte-colony stimulating factor (G-CSF), which helps your bone marrow make more white blood cells. You will receive G-CSF by injection or IV infusion until your blood counts recover.

The table below shows your treatment schedule:

Conditioning Regimen A	Days -12 to -10	Days -9 to -6	Days -5 to -4	Days -3 to -2	Day -1	Day 0	Day 7+
P-rATG	X				Rest		
TBI		X					
Thiotepa			X				
Cyclophosphamide				X			
Allo-HCT						X	
G-CSF							X

Conditioning Regimen B only: On Days -9 to -7, you will receive busulfan by IV infusion. Each infusion will last about 3 hours. On Days -6 and -5, you will receive melphalan and fludarabine together by IV infusion. Each infusion will last about 30 minutes. After that, you will receive fludarabine alone on Days -4 to -2.

You will rest the day before your transplant (Day -1), and you will not receive any treatment on this day.

Starting 7 days after your transplant, you will receive a standard medication called granulocyte-colony stimulating factor (G-CSF), which helps your bone marrow make more white blood cells. You will receive G-CSF by injection or IV infusion until your blood counts recover.

The table below shows your treatment schedule:

Conditioning Regimen B	Days -12 to -10	Days -9 to -7	Days -6 to -5	Days -4 to -2	Day -1	Day 0	Day 7+
P-rATG	X				Rest		
Busulfan		X					
Melphalan			X				
Fludarabine			X	X			
Allo-HCT						X	
G-CSF							X

<u>Exams, Tests, and/or Procedures</u>
You will have exams, tests, and/or procedures during the main study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

Tests and procedures that are being done for research purposes include:

- Blood collection for pharmacokinetic (PK) testing, which will look at the way your body absorbs, distributes, and gets rid of the P-rATG. You will give blood (about 1 teaspoon each time) at the following times:
  - Day -12: 15-30 minutes after your dose of P-rATG
  - Day -11: Within 30 minutes before your dose of P-rATG and 15-30 minutes after your dose
  - Day -5: In the morning, when you give blood for routine tests
  - Day 0: In the morning, when you give blood for routine tests
  - Day 7: In the morning, when you give blood for routine tests
- Questionnaire (optional) that asks about your quality of life, your symptoms, and how your disease is affecting your daily life. It will take about 20 minutes to complete this questionnaire, which will be on paper or electronic. You will complete the questionnaire at the following times:
  - Days 0, 7, 14, 21, 30, and 45

- Additional blood samples approximately 1 tablespoon will be collected for correlative research studies. We will only collect these samples only if you have consented to protocol #06-107.
  - Days 30,60,100,120,150, and 180.

End-of-Treatment and follow-up visits:

You will have follow-up evaluations while you are in the hospital after your transplant procedure. After you are released from the hospital, you will return to the clinic so the study doctor and study team can check your health and see if you are having any side effects from the conditioning regimen and transplant. The study doctor and the study team will continue to follow your health for at least 1 year after your transplant. This follow-up will be part of your standard care.

The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

Procedures that are being done for research purposes include:

- Questionnaire (optional) that asks about your quality of life, your symptoms, and how your disease is affecting your daily life. It will take about 20 minutes to complete this questionnaire, which will be on paper or electronic. You will complete questionnaires at the following times:
  - Monthly for one year (Months 2-12)
  - Once every 3 months for 2 years (Years 2-3)

A Study Calendar that shows how often you will have these exams, tests, and procedures is provided at the end of this consent form. The calendar also includes exams, tests, and procedures that are part of your usual care.

Will I receive the results of my research tests?

You will not receive the results of any tests done for research purposes during this study.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss

The drugs and radiation used in this study may affect how different parts of your body work, such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood throughout the study, and he or she will let you know if changes occur that may affect your health.

The drugs may cause an allergic reaction. Symptoms of allergic reactions include hives or skin rash, swelling of the face, difficulty breathing, nausea, vomiting, or low blood pressure (causing you to feel faint). Allergic reactions may be mild or severe. Rarely, these reactions may lead to death.

There is also a risk that you could have side effects from the study treatment/study approach.

Important information about side effects:
- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it difficult for you to have children.
- Some side effects may be mild. Others may be very serious, and may even result in death.

Important information about how you and the study doctor can make side effects less of a problem for you:
- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study treatment to try to reduce your side effects.

The tables below show the most common and the most serious side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible side effects of rATG:

Common, some may be serious In 100 people receiving rATG, more than 20 and as many as 100 may have:
• Fever, shaking, chills, and lowered blood pressure • Skin rash and itching • Headache • High blood pressure • Decreased number of white blood cells, which may increase your risk of infection • Decreased number of platelets (blood cells that help with clotting), which increases the risk of bleeding and/or bruising. You may receive a platelet transfusion to reduce the risk of bleeding or the rupture of a blood vessel, which may be life-threatening. • About 30% of people treated with rATG will develop a late immune reaction (serum sickness) 3-10 days after receiving the infusion. This reaction may lead to severe skin rashes, sores in the mouth and vagina, pain and swelling of the joints, or kidney damage. This condition is temporary and reversible, but it may

Common, some may be serious In 100 people receiving rATG, more than 20 and as many as 100 may have:
require prolonged treatment with corticosteroids (a type of anti-inflammatory drug).

Occasional, some may be serious In 100 people receiving rATG, between 4 and 20 may have:
• Abnormal heartbeat • Allergic reaction: Symptoms include nausea, vomiting, skin reactions (hives or rash), difficulty breathing, or low blood pressure (causing you to feel faint). Allergic reactions could be mild or severe, and they may lead to permanent disability or death. If you have any of these symptoms, the study doctor will interrupt (or stop) the infusion of rATG into your vein. The study doctor may give you medications such as antihistamines and steroids to treat your symptoms.

Rare, and serious In 100 people receiving rATG, 3 or fewer may have:
• Life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Reproductive risks: You should not get pregnant, breastfeed, father a baby, or donate sperm while you are in this study. The drugs and radiation used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control or pregnancy prevention to use while you are in this study. You must continue to use these methods until your blood cell counts and immune system have recovered after your allo-HCT. Recovery times can be different for different people; your study doctor will let you know when you can stop using these birth control methods.

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Tell the study doctor about:
  - All medications and any supplements you are taking
  - Any side effects from these medications or supplements
  - Any doctor visits or hospital stays outside of this study
  - Whether you have been or are currently in another research study.

- If you chose to take part in the optional quality of life questionnaire let the study doctor know if you skipped or chose not to answer any of the questions in the questionnaire/survey.

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center (MSK). There are no known investigator and/or institutional conflicts of interest for this study.

What are the costs of taking part in this study?

You will not have to pay for the P-rATG, TBI (if applicable), chemotherapy, or tests and procedures done only for research purposes, as described above in *What extra tests and procedures will I have if I take part in this study?* These tests and procedures include:

- Blood collection and testing for research purposes
- Optional study questionnaire

It is possible that the drugs given in this study may not continue to be supplied while you are in the study. This possibility is unlikely, but if it occurs, your study doctor will talk with you about your options.

You and/or your health plan/insurance company will have to pay for all the other costs of treating your cancer while you are in this study. These charges include the costs of allo-HCT, G-CSF, insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Although you do not have to pay for P-rATG or chemotherapy, the cost of getting the drugs ready and giving them to you is not paid by the study sponsor, so you or your insurance company may have to pay for this.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

Will I receive payment for taking part in this study?

You will not be paid for taking part in this study.

Your biospecimens (blood) may be used in the development of new tests, drugs, or other products for sale. If they are, you will not receive any payment from the sale of these products.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

In the future, your information (data) and biospecimens may be de-identified, which means that your data and/or biospecimens will be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your de-identified information and biospecimens may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or Social Security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Optional Quality of Life Study

If you choose to take part in this optional Quality of Life study, you will be asked to fill out a form that includes questions about your physical and emotional well-being.

Researchers will use this information to learn more about how cancer and cancer treatment affect people. You will be asked to fill out this form pre and post transplantation. The method of completion will occur via paper or electronic tool or via MSK patient portal (MSK Engage). Participants will receive a message through the MyMSK portal and/or text alert (when activated) when survey is assigned to them.

Each form will take about 20 minutes to complete. The forms include questions about things like sleep disturbance and physical function. You may feel uncomfortable answering some of the questions, and you may skip any questions that you do not want to answer.

Please check Yes or No. Your medical care will not be affected, no matter what you decide to do.

I agree to fill out the forms for this Quality of Life study:

❑ Yes ❑ No

This is the end of the section about the Optional Study

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

A Modified Dose of Rabbit Anti-thymocyte Globulin (rATG) in Children and Adults Receiving Treatment to Help Prepare Their Bodies for a Bone Marrow Transplant

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- Any health information or clinical data associated with your biospecimens, if the information or data could be reasonably used to identify you. This information or data will be shared only if you have agreed to it by signing this informed consent document.
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigators: Kevin Curran, MD; Michael Scordo, MD; and Suzanne Wolden, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study intervention.
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to the parts of your medical record that are unrelated to this study at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or to his/her Legally Authorized Representative (LAR). In my judgment, and in that of the participant or his/her LAR, sufficient information, including risks and benefits, was provided for the participant or his/her LAR to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's (or Legally Authorized Representative's [LAR's)]) statement

I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant/LAR must personally sign and date		
Participant/LAR signature		**Date:**
Participant/LAR name (Print)		
LAR relationship to participant		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's (or LAR's) language, and I confirm that the consent discussion was appropriately interpreted for the participant (or LAR).
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____

(The name of the witness must be documented in the EMR.)

Interpreter (if required)

Name of interpreter (if present): _____

ID number (if phone interpreter): _____

(The interpreter's name or ID number must be documented in the EMR.)

The participant/Legally Authorized Representative must be provided with a **signed copy** of this form.

Memorial Sloan Kettering Cancer Center
IRB Number: 21-193 A(6)
Approval date: 31-Aug-2022

Participant Assent for Clinical Research

Assent is required for a minor age 7 to 17 and for a participant with mildly impaired decision-making capacity.

Consenting Professional Must Personally Sign and Date		
Consenting Professional's Statement I have explained the study to the participant in age-appropriate terms and he/she agreed to take part in the study. He/she should sign and date below in the participant section. I have given a copy of this form to the participant and his/her Legally Authorized Representative (LAR). ☐ Check the box if the participant verbally agreed to take part but declined to sign or is unable to sign.		
Signature of consenting professional obtaining assent		**Date:**
Consenting professional name (printed)		
Participant Should Personally Sign and Date		
Participant's Statement I have read this consent or it was explained to me. All my questions have been answered. I agree to be in this research study.		
Participant signature		**Date:**

This form must be accompanied by an IRB-approved consent form signed by a Legally Authorized Representative.

Study Calendar:

This calendar shows the exams, tests, and procedures that will be done as part of this research study, as well as the tests and procedures that are part of your usual care.

Exam/test/ procedure	Screen-ing	Day (D) -12	D -11	D -5	D 0	D7	D 14	D 21	D 30	D 45	D 60	D 75	D 100	D 120	D 150	D 180	D 270	D 365	Year 2	Year 3
Physical exam, medical history	X																			
Dental evaluation	X																			
Questionnaires (optional)	X				X	X	X	X	X				X monthly (Months 2-12)					X	X 4 times a year	X 4 times a year
Pregnancy test, if needed	X																			
Routine urine test	X																			
Electrocardiogram	X																			
Echocardiogram	X																			
Lung function test	X																			
Routine blood tests	X				X	X	X		X		X		X			X	X	X		
Spinal tap and bone marrow aspiration and/or biopsy	X								X				X			X		X		
Imaging scans	X								X				X			X		X		
Research blood tests		X	X	X	X	X														
Correlative Research Blood [1]									X		X		X	X	X	X				

1.Blood sample collection for correlative research studies during days 30, 60, 100, 120,150, and 180. Participants will be enrolled onto protocol #06-107


1884