Certification of Completion of the Informed Consent

IRB #

Title:

I have discussed the "Informed Consent for Participation in Research Activities" in its entirety for the above referenced research study, with the research participant listed below (or the research participant's legally authorized representative). During the review of the consent form, the possible benefits, risks and discomforts involved in his/her participation on the study, as well as potential alternatives were reviewed.

The research participant has been encouraged to ask questions, and all questions asked by the participant have been answered. The research participant affirmed that he/she has received all information that he/she desires at this time, and a copy of the signed consent form has been provided to the participant.

| PRINTED NAME of Person Obtaining Informed (Consenter) | SIGNATURE | TITLE | DATE | TIME |
|---|---|---|---|---|
| | | | | |

# ADULT INFORMED CONSENT

**COH Protocol # 21016**

**TITLE:** Phase I Study of Escalating Doses of 90Y-DOTA-anti-CD25 Basiliximab Monoclonal Antibody Added to the Conditioning Regimen of Fludarabine, Melphalan and Organ Sparing Total Marrow and Lymphoid Irradiation (TMLI) as Conditioning for Allogeneic Hematopoietic Cell Transplantation in Patients with High-Risk Acute Leukemia, Myelodysplastic Syndrome, or non-Hodgkin's Lymphoma

**Version date:** 11/02/2023

**PRINCIPAL INVESTIGATOR:** Jeffrey Wong, MD

**24-HOUR TELEPHONE NUMBER:** (626) 256-HOPE (4673) ext. 95200
**DAY TIME TELEPHONE NUMBER FROM THE HOURS OF 8:00 AM TO 5:00 PM:** (626) 256-HOPE (4673) ext. 82405 (Hematology), ext. 82247 (Radiation Oncology)

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## EXPERIMENTAL PARTICIPANT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study, also known as an experiment or clinical trial. As a research participant, you have the following rights:

1. To be told what the research study is trying to find out.
2. To be told what will happen to you and whether any of the procedures to be used are different from what would be used in standard practice.
3. To be told about the discomforts, side effects and risks of the things that will happen to you as part of the research study.
4. To be told if you can expect any benefit from participating in the research study.
5. To be told of the other choices you have and how they may be better or worse than being in the research study.
6. To be told what medical treatment is available if any complications arise.
7. To be allowed to ask any questions concerning the research study, both before agreeing to be in the study and during the course of the study.
8. To refuse to participate in the research study or to change your mind about participation after the study is started. To be informed that this decision will not affect your right to receive the care you would receive if you were not in the study.
9. To receive a copy of the signed and dated research study consent form.
10. To be free of pressure when considering whether you wish to agree to be in the research study.

# ADULT INFORMED CONSENT

**COH Protocol # 21016**

**TITLE:** Phase I Study of Escalating Doses of 90Y-DOTA-anti-CD25 Basiliximab Monoclonal Antibody Added to the Conditioning Regimen of Fludarabine, Melphalan and Organ Sparing Total Marrow and Lymphoid Irradiation (TMLI) as Conditioning for Allogeneic Hematopoietic Cell Transplantation in Patients with High-Risk Acute Leukemia, Myelodysplastic Syndrome, or non-Hodgkin's Lymphoma

**PRINCIPAL INVESTIGATOR:** Jeffrey Wong, MD

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**KEY INFORMATION**

You are invited to participate in a research study because you have High-Risk Refractory or Relapsed Acute Leukemias (type of blood cancers), Myelodysplastic Syndrome (disruption of blood cell production), or non-Hodgkin's Lymphoma. The purpose of this research study is to investigate what is the maximum tolerated or recommended dose of the study treatment, *$^{90}$YDOTA-anti- Basiliximab Monoclonal Antibody (a targeted form of radiation therapy)*, while receiving fludarabine, melphalan (common drugs used to prepare the bone marrow to receive the transplanted cells) and a type of targeted radiation therapy known as Total Marrow and Lymphoid Irradiation (TMLI) (also used to prepare the bone marrow to receive the transplanted cells).These treatments will be described in further detail later in this consent form. The information we learn by doing this research study may help us learn more about whether this investigational treatment combination can help those with high-risk leukemias, myelodysplastic syndrome, or non-Hodgkin's Lymphoma.

Participants in this study will be given a regimen of *$^{90}$YDOTA-anti- Basiliximab Monoclonal Antibody (the study treatment)* while also receiving supplemental treatment in fludarabine, melphalan, and TMLI. While you are on this study, you will be closely monitored through lab tests, consultations, and evaluations to see if you can tolerate the study treatment while receiving the supplemental treatment.

Participation is expected to last 2 years.

The major risks associated with study include bone marrow suppression (leading to decrease production of blood and immune cells), mucositis (a common side effect of chemotherapy resulting from inflammation of the moist lining of digestive tract ), nausea, vomiting, diarrhea, hair loss, damage to the lungs, rash, inflammation of blood vessels, fever, itchiness, anorexia (serious diminished appetite), constipation, and more. A full list of details of know side effects can be found later in this consent under the "**What are potential risks and discomfort?**" section.

You do not have to join this research study. You can choose to receive alternate methods to treat your leukemia, myelodysplastic syndrome, or non-Hodgkin's lymphoma instead of participating on this study. If you are interested in learning more about this study, please continue to read below.

## INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you have high risk refractory or relapsed leukemia, myelodysplastic syndrome, or non-Hodgkin's lymphoma. We hope to learn what will be the maximum tolerated dose/recommended dose of the study treatment $^{90}$YDOTA-anti- Basiliximab Monoclonal Antibody when combined with melphalan, fludarabine, and TMLI as drugs/radiation to prepare the bone marrow for stem cell transplantation. This research study is looking at this combination of treatment as a possible future pattern of giving treatment for this diagnosis.

This research study is sponsored by City of Hope.

It is expected that about 12 people will take part in this research study.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future. Please take as much time as you need to read the consent form. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

## A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Phase I clinical trial, which tests the safety of an investigational (experimental) intervention and also tries to define the appropriate dose of the investigational intervention to use for further studies. "Investigational" means that the intervention is being studied.

The FDA (the U.S. Food and Drug Administration) has not approved the combination of $^{90}$YDOTA-anti-Basiliximab Monoclonal Antibody and TMLI as a preparative regimen before HCT for treatment of your disease.

The FDA (the U.S. Food and Drug Administration) has approved Melphalan and Fludarabine as a drugs to prepare your bone marrow to receive the donated stem cells as treatment for your disease and other blood cancers. Additionally, basiliximab is FDA approved for the prevention of organ rejection after kidney transplant.

The names of the study interventions involved in this study are:

- $^{111}$In-DOTA-anti- Basiliximab Monoclonal Antibody (a targeted form of radiation therapy)
- $^{90}$YDOTA-anti- Basiliximab Monoclonal Antibody (a targeted form of radiation therapy)
- Indium-111 ($^{111}$In) is a radioactive substance used in diagnostic imaging tests and Yttrium-90 ($^{90}$Y) is a radioactive substance that is used to treat different types of cancer.
- TMLI (a different type of targeted radiation therapy)
- Melphalan (a common chemotherapy drug used to prepare the bone marrow to receive the transplanted cells)
- Fludarabine (a common chemotherapy drug used to prepare the bone marrow to receive the transplanted cells)

In this research study, we will be looking to find what is the maximum tolerated dose for the study treatment, $^{90}$Y-DOTA-anti- Basiliximab Monoclonal Antibody in combination with a fixed dose of TMLI, Melphalan and Fludarabine. There are three dose levels planned with at least three patients per dose level. For each dose level, we will increase the dose of the $^{90}$Y-DOTA-anti- Basiliximab Monoclonal Antibody as tolerated to find the highest tolerated dose. We hope to use this combination as part of the combination of treatment to prepare the bone marrow to receive the transplanted cells for better transplant outcomes for treatment of high-risk leukemias, myelodysplastic syndrome, or non-Hodgkin's lymphoma.

Basiliximab is an antibody directed against CD25, a protein that is found on the surface of certain leukemia cells. Basiliximab is approved by the FDA (Food and Drug Administration) for the treatment of rejection after kidney transplantation. Basiliximab has also been used to treat the disease graft versus host disease (GVHD), which can occur after transplant of blood or marrow from a donor. Graft versus host disease is a condition that might occur after a stem cell transplant using stem cells from another person. In GVHD, the donated stem cells view the recipient's body as foreign, and the donated cells attack the body. It is experimental to use basiliximab in a preparative regimen prior to transplant. In this study, a radioactive substance called Yttrium-90 will be attached directly to the basiliximab, which is an antibody-radiation combination. The purpose of the study is to see if this experimental antibody-radiation combination can be combined with TMLI and the chemotherapy agents fludarabine and melphalan. The use of a drug that is an antibody-radiation combination is called radioimmunotherapy (RIT). This trial is the first time this approach has been used in patients with leukemia, myelodysplastic syndrome, or non-Hodgkin's lymphoma.

## B. WHAT IS INVOLVED IN THE STUDY?

If you decide to take part, this is what will happen:

Since we are looking for the highest dose of the study drug that can be administered safely without severe or unmanageable side effects in participants that have high risk acute leukemias, myelo

dysplastic syndrome, or non-Hodgkin's lymphoma, not everyone who participates in this research study will receive the same dose of the study drug. The dose you get will depend on the number of participants who have been enrolled in the study before you and how well they have tolerated their doses.

**Before the research starts (screening):**

After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

- **A medical history,** which includes questions about your health, current medications, and any allergies.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **An assessment of your tumor** by one or more of the following standard assessment tools: X-ray, CT (Computerized Tomography) scan, MRI (Magnetic Resonance Imaging) or PET (Positron Emission Tomography) scans
- **Blood Samples:**
    1) **(About 4-5 teaspoons**) will be taken for routine blood counts, blood chemistry (to evaluate how your organs are working) and other laboratory tests,
    2) **(About 4-5 teaspoons)** will be taken for infectious diseases, HIV Test, and test for Hepatitis A, B, and C, etc. The results of these tests will appear in your medical record and will be shared with health care workers involved in your care. The test results will be shared with the study sponsor(s), its subcontractors and/or its agents to perform functions relating to the conduct of this research. When required by law, any positive results will be shared with a health authority (e.g., the State Department of Health).
- **Urine test.** Urine will be collected from you for routine laboratory testing to monitor your general health.
- **Pulmonary function test** to assess how your lungs are working.
- **Electrocardiogram (ECG or EKG),** a picture of the electrical action of the heart to assess how your heart is working.
- **MUGA scan** (a picture of the heart using a small amount of radioactive material injected into the bloodstream through a vein) or echocardiogram (a picture of the heart in motion using ultrasound or sound waves) to evaluate how your heart is working.
- **Bone marrow evaluation**. A bone marrow aspiration involves numbing an area of the hip and withdrawing a small sample of bone marrow from the hipbone by a needle. A bone marrow biopsy is similar except a sample of bone is also removed through the needle. You will be asked to sign a separate consent for this procedure.
- **Research Bone Marrow Biopsy and Aspirate (approximately 2 teaspoons)** will be collected at pre-study screening.

- **FDG-PET Imaging (Patients with non-Hodgkin's lymphoma)** to detect your cancer and stage your disease before treatment starts.

If these tests show that you are eligible to participate in the research study, you will begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

**Study Procedures:**

If you are eligible to participate in this research study, the following test and procedures will occur. A chart summarizing the timing of these tests and procedures is also provided below. Some tests and procedures may be part of your standard of care.

- **Clinical Exams:** During this visit you will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- **Performance status**, which evaluates how you are able to perform your daily usual activities.
- **An assessment of your tumor** by one or more of the following standard assessment tools: X-ray, CT (Computerized Tomography) scan, MRI (Magnetic Resonance Imaging) or PET (Positron Emission Tomography) scans
- **Photographs:** If your cancer is visible on your skin, photographs may be taken of your cancer to assess the response of your tumor to the treatment. Care will be taken to ensure these photographs do not reveal your identity.
- **Blood Samples:**
    1) **(About 4-5 teaspoons**) will be taken for routine blood counts, blood chemistry (to evaluate how your organs are working) and other laboratory tests
    2) **(About 1 teaspoon)** will be taken for research purposes, to check your blood for circulating levels of the protein sCD25.
- **Bone marrow evaluation**. A bone marrow aspiration involves numbing an area of the hip and withdrawing a small sample of bone marrow from the hipbone by a needle. A bone marrow biopsy is similar except a sample of bone is also removed through the needle. You will be asked to sign a separate consent for this procedure.
- **Research Bone Marrow Biopsy and Aspirate (approximately 2 teaspoons)** will be collected at screening and again at year 1 post-transplant.
- **Pulmonary function test** to assess how your lungs are working.
- **Electrocardiogram (ECG or EKG),** a picture of the electrical action of the heart to assess how your heart is working.
- **GVHD Assessment and Grading** to monitor you to see if you experience Graft Versus Host Disease (where your immune system attacks the transplant)

**Treatment Plan:**

Prior to receiving the stem cell transplant (about 14 or 15 days prior), you will receive an intravenous infusion (IV, into a vein) of basiliximab that will not be labeled with any radioactive substance. The reason for the infusion of unlabeled basiliximab is to allow it to attach to any sCD25 (a protein that is on the surface of some cells) that may be in your bloodstream and remove it from your blood prior to the infusion of the $^{111}$In/$^{90}$Y-labeled basiliximab. One to two hours later the same day, you will receive a dose of the study treatment $^{90}$Y-antiCD25 Basiliximab (combined with $^{111}$In) intravenously. During this time, the research doctor, nurse, and other research personnel will monitor you closely for adverse reactions for several hours following the dose. If you feel fine and it is determined by the research staff that you are well and stable, you will complete that clinic visit.

A total of three imaging scans will be done after you receive the $^{111}$In/$^{90}$Y-labeled radioactive antibody. The scans that will be done are called planar and SPECT nuclear scans, which are done on a scanner in radiology that can detect the Indium-111 isotope that was injected in your body. The planar scans show a 2 dimensional view of the body, and the SPECT scans show a 3 dimensional view. These scans will be done as an outpatient at about 0-2 hours, 1 day, and 5/6 days after the $^{111}$In/$^{90}$Y-labeled basiliximab infusion. The purpose of these scans is to collect data on where the radiation travels to within the body.

Additionally, a total of 4 blood samples (1 teaspoon at each time point) for research purposes will be collected at 1-2 hours and 3-4 hours post infusion, as well as at scan times of 1 day and 5/6 days after the infusion. The blood samples are needed to help your doctors determine how quickly the antibody leaves your body and to estimate the radiation dose to your body.

**Additional Treatments:**

In addition to the administration of study treatment described above, you will receive a combination treatment consisting of TMLI, Fludarabine, and Melphalan to also help prepare your bone marrow to accept the donated stem cells.

TMLI is a targeted radiation therapy that uses CT scan imaging to help better identify where treatment will be directed. It reduces radiation exposure to normal organs compared to other forms of radiation therapy used in transplantation, such as total body irradiation (TBI). It will be given to you 4 days in a row (1 week after the infusion of the study treatment).

Fludarabine, which is usually used as part of the preparative regimen before stem cell transplantation for treatment of leukemia, will be administered between 2 to 4 days prior to the transplant.

Melphalan, which is usually administered as part of the preparative regimen before stem cell transplantation for treatment of leukemia, will be given 2 days prior to the transplant.

The treatments using the standard medications Sirolimus and Tacrolimus will also be given to you to prevent graft-versus-host disease (GVHD), which is a common complication after stem cell

transplantation from a donor and happens as a result of donor immune cells attacking and destroying patient's tissues and cells.

Your health will be closely monitored to see how you react to all the treatments.

**Research Study Calendar (Pre-transplant):**

| Procedure | Pre-Study Screening | Day -15 or -14 | Day -14 or -13 | Day -9 | Day-8 | Day -7 | Day -6 | Day-5 | Day-4 | Day-3 | Day -2 | Day -1 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Medical History | X | | | | | | | | | | | |
| Physical exam/vital signs | X | | | | | | | | | | | |
| Height/weight | X | | | | | | | | | | | |
| Tests to examine your lungs' health | X | | | | | | | | | | | |
| Tests to examine your heart's health | X | | | | | | | | | | | |
| CT scan to identify if there are any lung infections | X | | | | | | | | | | | |
| **Laboratory Tests** | | | | | | | | | | | | |
| Blood and Urine Sample Collection | X | | | | | | | | | | | |
| **Treatment** | | | | | | | | | | | | |
| Basiliximab infusion | | X | | | | | | | | | | |
| $^{111}$In/$^{90}$Y-antiCD25 Basiliximab | | | | | | | | | | | | |
| $^{111}$In-antiCD25 Basiliximab nuclear scans | | X | X | X | | | | | | | | |
| TMLI (fixed dose) | | | | | X | X | X | X | | | | |
| Fludarabine | | | | | | | | | X | X | X | |
| Melphalan | | | | | | | | | | | X | |
| Sirolimus and tacrolimus | | | | | | | | | | | | X |
| **Study evaluations** | | | | | | | | | | | | |
| Research blood sample collection | | X | X | X | | | | | | | | |
| Research BM sample collection | X | | | | | | | | | | | |
| Blood draw for sCD25 | | X | | | | | | | | | | |

* Screening activities to occur within 30 days prior to start of protocol therapy

**Research Study Calendar (Post-transplant):**

| Procedure | Day 0 | Day +3 | Day +4 | Day +5 | Day +30 | Day +60 | Day +100 | Day +180 | Year 1 | Year 2 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Standard of care** | | | | | | | | | | |
| Physical exam/vital signs[1] | X | X | X | X | X | X | X | X | X | X |
| Weight[1] | X | X | X | X | X | | X | X | X | X |
| Blood Sample Collection | X | X | X | X | X | X | X | X | X | X |
| Tests to examine your lungs' health | | | | | | | | | X | X |
| Tests to examine your heart's health | | | | | | | | | X | X |
| Engraftment status | | | | | X | X | X | X | X | X |
| Bone marrow collection | | | | | X | | X[2] | X | X | X |
| GVHD assessment and grading | X | | | | X | X | X | X | X | X |
| **Treatment** | | | | | | | | | | |
| Stem cell infusion | X | | | | | | | | | |
| Tacrolimus/Sirolimus | | | | X | | | | | | |
| **Study intervention** | | | | | | | | | | |
| Toxicity and/or GvHD grading | X | | | | X | X | X | X | X | X |
| Blood draw for sCD25 | | | | | X | X | X | | X | |
| Research BM sample collection | | | | | | | | | X | |

1. Daily during admission until discharge, then in every clinic visit (diff to be done when valid differential can be run per lab rules)
2. For leukemia/MDS patients, not required at day 100. For non-Hodgkin lymphoma patients, only required at day 100.

**Planned Follow-up:**

As noted in the calendar, we would like to keep track of your medical condition for at least 2 years post-transplant. For this study, participation may conclude when any of the following occur:

- Completion of study activities (treatment and 2 years of follow-up after protocol treatment)
- Withdrawal of consent
- Participant is lost to follow-up. All attempts to contact the participant must be documented.
- At the discretion of the study doctor for safety, behavioral, study termination or administrative reasons.

## C. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study for about 2 years.

## D. WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are risks to taking part in any research study. One risk is that you may get a study dose of a drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects.

All cancer treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different cancer treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. You will be monitored closely for any severe, life-threatening side effects listed below. Some of these side effects may be permanent. Appropriate medical care will be provided, if necessary, including additional treatment, hospitalization and/or surgery.

Possible risks and discomforts you could experience during this study include:

### Risks of Basiliximab

To manufacture the drug basiliximab, some materials that come from human and animal blood are used. Although contaminants are removed from the final products during the manufacturing process, however it is not possible to rule out the risk of infection from potential unknown contaminants remaining in the final products. While this risk is unlikely, it is still present.

Basiliximab is a human/mouse protein, also known as a monoclonal antibody, that is a type of protein made in the laboratory that can bind to substances in the body, including cancer cells. Because it is partly made of mouse proteins, it is considered a foreign protein, and its use can stimulate a person's immune system to make antibodies against it (called human anti-mouse antibodies or HAMA). The occurrence of HAMA could limit the future use of other mouse-based antibody products for diagnostic purposes or other experimental treatments. There is a small possibility of development of these antibodies. One percent of adult patients treated with basiliximab in prior studies developed low levels of these antibodies that did not affect the effectiveness or safety and were not associated with any adverse effects.

| **Likely**<br><br>(May happen in more than 1 in 10 patients)<br><br>These are short-term side-effects that can be treated with medication and are reversible. | **Rare, but serious**<br><br>(May happen in less than 2 in 100 patients)<br><br>Your blood counts will be closely monitored in order to avoid the potentially life-threatening complications. These side effects have always improved after treatment was stopped. |
|---|---|
| • Abdominal pain<br>• back pain<br>• constipation<br>• coughing<br>• dizziness<br>• fever or chills<br>• loss of energy or weakness<br>• painful urination<br>• shortness of breath<br>• sore throat<br>• swelling of the ankles, body, face, feet or lower legs<br>• trembling or shaking of the hands or feet<br>• vomiting<br>• white patches in the mouth or throat or on the tongue | • severe allergic reactions<br>  ○ rash<br>  ○ hives<br>  ○ difficulty breathing<br>  ○ tightness in the chest<br>  ○ swelling of the mouth, face, lips, or tongue<br>• Abnormal vision<br>• Agitation, such as being irritable<br>• Anxiety<br>• Bleeding, tender or enlarged gums<br>• Blood in the stool<br>• Bruising<br>• Chest pain<br>• Depression<br>• Difficulty in urinating<br>• Fatigue<br>• Itching<br>• Numbness or pain in the legs<br>• Skin rash<br>• Sores in the mouth<br>• "Stocking and gloves" sensation of the hands or feet<br>• Tingling in the hands or feet |

**Risks associated with $^{111}$In-Basiliximab**

***In-111-basiliximab*** may cause temporary, reversible, allergic reactions, treatable with medication, that include the following: (Note: these side effects have been seen with Zevalin {another monoclonal antibody-radiation combination drug used to treat certain lymphomas}, therefore it is possible that they may be seen with In-111-/Y-90-basiliximab.)

| **Likely**<br><br>(May happen in more than 1 in 10 patients)<br><br>These symptoms, if severe, will be treated by discontinuing the infusion and giving appropriate medications, including steroids and additional anti-histamines. | **Less Likely**<br><br>(May happen in less than 1 in 10 patients) | **Rare, but serious**<br><br>(May happen in less than 2 in 100 patients) |
|---|---|---|
| • Hives<br>• Itching<br>• Rash<br>• Difficulty breathing<br>• Chills | • Nausea<br>• Vomiting<br>• Angioedema (swelling in parts of the body, for example the face) | • Aplastic anemia (a condition in which the bone marrow does not make enough new cells to replenish blood cells)<br>• Bronchiolitis obliterans (lung disorder)<br>• Abnormal vision<br>• Reactivation of hepatitis<br>• Death |

**Risks associated with $^{90}$Y-Basiliximab**

| **Likely**<br><br>(May happen in more than 1 in 10 patients) | **Less Likely**<br><br>(May happen in less than 1 in 10 patients) |
|---|---|
| • Additional lowering of the<br>  ○ Red blood cells (anemia, which can make you feel more tired)<br>  ○ White blood cells (which can make it harder to fight infection)<br>  ○ Platelets (which can make it harder to stop bleeding) | • Chills<br>• Nausea<br>• VomitingAngioedema (swelling in parts of the body, for example the face) |

The Indium-111 and the Yttrium-90 infusion that you will receive in this study is specifically designed to target additional radiation therapy to your leukemia. It will therefore expose you to additional low amounts of radiation. The estimated amount of additional radiation therapy is significantly less than that from TMLI described below. The additional low amounts of radiation you will receive with the Indium-111 and the Yttrium-90 is slightly more than you would receive if you were not in the study. Every day, people are naturally exposed to low levels of radiation that come from the sun and the environment. This type of radiation is called “background radiation”. No one knows for sure whether exposure to low amounts of radiation is harmful for your body. However, scientists believe that being exposed to too much radiation can cause harmful side effects, including the potential to cause a new cancer.

**Risks of Total Marrow Irradiation (TMLI);** In this study TMLI is combined with the drugs melphalan and fludarabine. The side effects listed could potentially be due to the combined effects of each agent since the can have similar side effects. The TMLI may contribute to fatigue, skin erythema (redness), and temporary hair loss. You are also likely to have low blood counts with the risks and possible need for blood and platelet transfusion. Other side effects that may occur while you are receiving treatment include nausea, vomiting, diarrhea, sores in the mouth, esophagitis (inflammation of the tube that goes from the throat to the stomach), loss of appetite, and pneumonitis (inflammation of the lungs). These side effects are usually temporary and may be treated with other medications.

**Late Effects:** Side effects may occur several months to many years after your transplant. Potential late toxicities may include permanent sterility (inability to conceive or to father a child), endocrine problems, such as low thyroid, that would require thyroid medication, cataract formation (cloudy area in the eye that disturbs vision) possibly requiring surgical removal of the cataract, bone marrow failure (failure of the bone marrow to grow), and secondary cancer. Some of the rare late side effects, such as inflammation of the lungs and bone marrow failure, could be fatal. Rarely, this may cause you to develop another cancer, generally 10 to 15 years after the transplant. Secondary cancers are often very difficult to treat and can be fatal. The long-term effects upon the heart is that it may increase the risk of coronary artery disease.

**Risks associated with Fludarabine**

| **Likely**<br><br>(May happen in more than 1 in 10 patients) | **Less Likely**<br><br>(May happen in less than 1 in 10 patients) | **Rare, but serious**<br><br>(May happen in less than 2 in 100 patients) |
|---|---|---|
| • Temporary low blood cell counts. Low white blood counts increase the risk of infection and might require antibiotics and possibly hospitalization. Low red blood counts cause anemia that would make you feel tired and might require transfusions. Low platelet counts increase the risk of bruising and bleeding and might require transfusions.<br>• Nausea and vomiting<br>• Tiredness | • Changes in vision<br>• Diarrhea<br>• Numbness and tingling in hands or feet | • Agitation or nervousness (temporary, usually disappears when the drug is discontinued.)<br>• Pneumonia (infection of the lung), which may be temporary and be treated with additional medication and hospitalization may occur<br>• Confusion<br>• Cough<br>• Difficulty breathing<br>• Weakness<br>• Severe brain injury and death (permanent)<br>• Heart failure, which may be permanent and death can occur |

**Risks associated with Melphalan**

| **Likely**<br><br>(May happen in more than 2 in 10 patients) | **Less Likely**<br><br>(May happen in less than 2 in 10 patients) | **Rare, but Serious**<br><br>(May happen in less than 2 in 100 patients) |
|---|---|---|
| • Loss of appetite<br>• Constipation<br>• Diarrhea<br>• Nausea (feeling sick to your stomach) and vomiting (throwing up)<br>• Temporary hair loss<br>• Sensitive skin | • Changes in heart beat that cause you to be dizzy, faint and short of breath<br>• Hepatitis (swelling of the liver)<br>• Kidney failure<br>• Weight loss<br>• Feeling weak | • Allergic reaction<br>• Lung infection<br>• Scarring of lung tissue<br>• Seizure<br>• Vasculitis (inflammation of blood vessels)<br>• Low blood pressure<br>• Excessive perspiration (or sweating)<br>• Sterility (unable to have children)<br>• Liver damage<br>• Heart stops beating<br>• Cancer of bone marrow cells |

| | | |
|---|---|---|
| • Infection<br>• Low number of white blood cells<br>• Low number of platelets in the blood with increased risk of bleeding<br>• Anemia (low number of red blood cells)<br>• Skin breakdown (if drug leaks from vein)<br>• Sores in the mouth<br>• Esophagitis (inflammation of the tube that goes from the throat to the stomach)<br>• Permanent sterility (inability to conceive or to father a child),<br>• Bone marrow failure (failure of the bone marrow to grow)<br>• Secondary cancer.<br>• Some of the rare late side effects, such as bone marrow failure, could be fatal. Secondary cancers are often very difficult to treat and can be fatal. | | |

**Risks associated with Tacrolimus**

| **Likely**<br>(May happen in more than 2 in 10 patients) | **Less Likely**<br>(May happen in less than 2 in 10 patients) | **Rare, but serious**<br>(May happen in less than 2 in 100 patients) |
|---|---|---|
| • Kidney problems<br>• Low magnesium, calcium, and potassium in the blood<br>• High blood pressure<br>• Tremors (shaking)<br>• High cholesterol<br>• Low number of platelets in the blood with increased risk of bleeding<br>• Infection | • Nausea and vomiting<br>• Liver problems<br>• Foggy thinking<br>• Trouble sleeping<br>• Unwanted hair growth<br>• Confusion<br>• Reversible posterior leukoencephalopathy syndrome [RPLS]/ Posterior reversible encephalopathy syndrome [PRES] (headache, confusion, seizures, and vision loss caused by very high blood pressure that comes on quickly) | • Seizures<br>• Changes in vision<br>• Feeling dizzy<br>• The body stops making red blood cells (can lead to anemia)<br>• Lymphoproliferative disorder (the body makes too many lymphocyte cells) |

**Risks associated with Sirolimus:** Sirolimus is used with other medications to prevent organ transplant rejection.

| **Likely**<br>(May happen in more than 2 in 10 patients) | **Less Likely**<br>(May happen in less than 2 in 10 patients) | **Rare, but serious**<br>(May happen in less than 2 in 100 patients) |
|---|---|---|
| • High blood pressure<br>• Nausea (feeling sick to your stomach)<br>• Diarrhea and/or constipation<br>• Infection<br>• Fever<br>• Liver or kidney problems<br>• Joint pain<br>• Weight gain<br>• High cholesterol<br>• Acne | • Chest pain<br>• Insomnia (unable to sleep)<br>• Upset stomach or vomiting<br>• Shortness of breath<br>• Low blood counts<br>• Skin rashes or hives<br>• Slow wound healing | • Low blood pressure<br>• Lung problems, including asthma<br>• Loss of appetite<br>• Serious infections<br>• Blood clots<br>• Skin problems (such as a rash)<br>• Kidney failure<br>• Secondary cancers<br>• Bone degeneration (necrosis)<br>• Muscle pain |

Since the effect of the study drug(s) taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

**Risks Associated with Blood Draw**

Risks of blood draws include mild pain or discomfort, bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).

Cancer research often includes biopsies, scans, x-rays that are also provided as routine care. The following describes the side effects of procedures done only for the purposes of research.

**Risks Associated with Biopsies:**

Biopsies are normally performed under the guidance of an imaging technique. Each procedure requires a separate consent prior to the biopsy. The risks may include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

**Risks Associated with Bone Marrow Biopsies:**

For this procedure, a numbing drug is injected into the skin over one of your hipbones. A needle is then inserted into the hipbones and a small piece of bone is removed. The risks may include:

- Moderate pain and discomfort
- Bleeding at the biopsy site
- Scarring at the biopsy site
- Rarely, an infection at the biopsy site
- Rarely, nerve injury at the biopsy site

**Risks Associated with Bone Marrow Aspiration:**

For this procedure, a numbing drug is injected into the skin over the same hipbone. A needle is then inserted into the hipbone and a sample of bone marrow fluid is removed. Risks of this procedure are small, but may include:

- Pain from the needle sticks
- Pain from aspirating the bone marrow with a syringe
- Bleeding
- Infection
- Local nerve damage

**Risks Associated with Catheter Placement**: Complications of central venous catheters include blood clots and infection. Clotting may require removal of the catheter or treatment of the clot by injecting a medicine that dissolves blood clots. If you develop an infection, you will require treatment with antibiotics. If the catheter is placed under the collarbone, uncommon side effects include swelling of the face and arm and/or lung collapse. If the lung collapses, it may be necessary to place a tube between the ribs to allow the lung to re-expand.

**Radiation Risks Associated with Scans:**

While you are in this research study, SPECT scan utilizing radioactivity will be used to evaluate the study agent traveling through your body. The frequency of these exams is slightly greater than what you would receive as standard care. In the long term, over many years, there is a very low risk of developing a new cancer as a result of the radiological evaluation and treatment for your cancer. Certain types of drugs or combinations of these drugs with radiation may further slightly increase the risk of developing a new cancer. This risk is described above, in the section about the risks associated with the study treatment.

The imaging SPECT scan that you will receive in this study will expose you to low amounts of radiation. Every day, people are naturally exposed to low levels of radiation that come from the sun and the

environment. This type of radiation is called “background radiation”. No one knows for sure whether exposure to low amounts of radiation is harmful for your body. However, scientists believe that being exposed to too much radiation can cause harmful side effects, including the potential to cause a new cancer.

**Incidental Findings:**

It is possible the research procedures could find a medical problem unrelated to the purpose of this study that you did not know about before. If during the research procedures we learn information that may be important for you to know about, such as the possibility of a previously unknown medical condition, we will tell you. You may authorize the release and communication of the findings to your personal doctor. These findings may require additional testing or treatment. You will be responsible for the cost of any additional tests or related treatment.

Results of genetic research will not be used in your medical care. The results will not be given to you, the study doctor, or your personal doctor.

**Reproductive Risks:**

We do not know whether this study drug might hurt an unborn child. While participating in this research study, you should not become pregnant or father a baby, and should not nurse a baby. We can provide counseling about preventing pregnancy for either male or female study participants. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

In the event that your partner becomes pregnant, it may be critical to share information regarding your participation in this research study with that person. Your research doctor should also be told if this happens. The study sponsor may want to collect data on your partner’s pregnancy.

You must use birth control while on this study. These are some birth control measures that you can use:

If you are pregnant or nursing a baby and do not want to stop, you cannot take part in this study. If you are a woman who can become pregnant, a urine pregnancy test will be obtained before treatment is started. If you are sexually active and capable of bearing or fathering a child, both you and your partner must agree to use two medically effective forms of birth control while you are on this study. The investigational drug(s) may involve risks to you (or to the embryo or fetus, if you or your partner become pregnant), which is currently unforeseeable.

You must use birth control while on this study. Acceptable medically effective forms of birth control are:

- Abstinence,
- Surgical sterilization (tubal ligation or hysterectomy for women, or vasectomy for men),
- Double-barrier methods (i.e. condoms, diaphragm, cervical cap, or sponge used with spermicidal gel or foam),

- Intrauterine device (IUD) (i.e. Progestin, Copper),
- Hormonal Contraceptives (Birth control patches, implants, pills, rings, or injections)

**Other Risks:**
Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

**Risks associated with Breach of Confidentiality***:*
There is a small risk that people who are not connected with this study will learn your identity or your personal information.

**Risks associated with Highly Sensitive Information:**
You are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, you could have problems getting a new job, keeping your current job, and finding housing, or getting insurance (health, disability, or life insurance).

Results of this genetic research will not be used in your medical care. The results will not be given to you, the study doctor, or your personal doctor. Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health, and may prevent discrimination by health insurers and employers based on genetic information. GINA is intended to ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health, and enable people to take part in research studies such as this without fear that their DNA information might be used against them by health insurers or their workplace. This protection does not extend to disability or life insurance. Additional information can be found at http://www.genome.gov/10002328.

## E. WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

## F. HOW WILL YOUR INFORMATION BE KEPT CONFIDENTIAL?

Any information learned from this study in which you might be identified will be confidential and disclosed only with your permission. Every effort will be made to keep any information collected about you confidential. However, it is impossible to guarantee that information about you will not be mistakenly released. If, despite our best efforts, identifying information about you is released, it could negatively impact you or your family members. This risk is small.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, City of Hope.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- Regulatory agencies such as the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the National Cancer Institute (NCI) in the U.S., and similar ones if other countries are involved in the study as required by law.

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

**Future Use of Research Information and Specimens**

In the future, the information or specimens that have been collected for this study might/will be de-identified, which means any information that could be used to identify you will be removed from the information or specimens. The de-identified information or specimens may be used for future research studies or shared with other researchers. You will not be informed of or asked to consent to these future research activities.

The information or specimens that have been collected for this study will not be used for future research studies or shared with other researchers beyond the research activities described in this consent form.

## G. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS RESEARCH STUDY?

There is no guarantee that you will receive any benefits from this study. The possible benefit of the study drug in the treatment of leukemia, myelodysplastic syndrome, or non-Hodgkin's lymphoma is not known. If you decide to participate in this study, your health will be monitored very closely. By being in this study, you will give doctors more information about how well the study drug works. It may help doctors understand your condition better and may help future patients with this medical condition.

## H. WHAT OTHER OPTIONS ARE THERE?

If you decide not to take part in this study, you have other choices. For example:

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

## I. ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

You will not be paid for participating in this study.

**Possible Commercial Products**
We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. Donors of blood, tissue and other biological materials do not retain any property rights to the materials. Therefore, you would not share in any money or other benefits that any entity might receive for these inventions or discoveries.

## J. WHAT ARE THE COSTS?

Taking part in this research study might lead to added costs to you or your insurance company.

The study treatment will be provided to you at no cost while you take part in the study. You and your health plan/insurance company will need to cover the cost of the infusion/injection of the study drug. It is possible that the study treatment) may not continue to be supplied while you are on the study. If this occurs, the research doctor will talk to you about your options.

Most of the tests, procedures, and/or drugs provided to you as part of this study are routinely used to treat your illness. You would receive these tests, procedures, and/or drugs even if you were not participating in this study. You or your health plan/insurance company will need to pay for this routine care. You will also be responsible for any co-payments or deductibles required by your health plan/insurance company. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs because you are in a research study. If your health plan/insurance company will not pay these costs, you will have additional expenses from being in this study, such as the costs associated with treating side effects.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- City of Hope Financial Support Services: 626-256-HOPE (4673), extension: 80258.

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

## K. WHAT HAPPENS IF YOU GET INJURED AS A RESULT OF THIS STUDY?

If you think you have been hurt by taking part in this study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form. City of Hope will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

**L. WHAT ARE YOUR RIGHTS IF YOU TAKE PART IN THIS STUDY AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?** Your participation in this research study is voluntary. You are free to withdraw your consent for participation in this study without any loss of benefits, penalty, or interference with any future treatment at City of Hope.

You can decide to stop at any time and you may still be treated at your hospital or clinic. Tell your study doctor if you are thinking about stopping or decide to stop. You should talk to the doctor about leaving the study before you decide so that he/she can find out if you are having any side effects from study treatment. Another reason to tell your doctor that you are thinking about stopping is so that he/she can talk to you about any other treatments that could be helpful to you.

If you decide to stop being in this study, you will still be asked to come back to the hospital or clinic for the end of treatment tests described above. You may also be asked to take part in the follow-up phone calls and/or visits. This information is important to make sure that there are no lasting side effects from the study treatment and to see if your cancer got better, stayed the same, or got worse after treatment.

**M. CAN YOU BE REMOVED FROM THE STUDY?**

You may be removed from this study without your consent for any of the following reasons: you do not follow the study doctor's instructions, at the discretion of the study doctor, the sponsor, your disease gets worse, or the sponsor closes the study. If this happens, the study doctor will discuss other options with you.

**N. WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?**

The principal investigator, Dr. Jeffrey Wong, responsible for your care or treatment, has offered to and has answered any and all questions regarding your participation in this research study. If you have any further questions or in the event of a research related injury, you can contact Dr. Wong at (626) 256-HOPE (4673) ext. 82247.

This study has been reviewed and approved by the Institutional Review Board (IRB). If you have any questions regarding your rights as a research participant, you may contact a representative of that Board, from the Office of Human Research Subjects Protection, at (626) 256-HOPE (4673) ext. 62700.

**P. SIGNATURE SECTION**

**SIGNATURE FOR CONSENT**: By signing this consent form, you are making a decision to participate in this research study. Your signature on this informed consent form indicates that you:

1. Have read and understood the information in this form.
2. Have had the information in this form explained to you.
3. Have had a chance to ask questions and these questions were answered to your satisfaction.
4. Have been informed that you will receive a copy of this signed consent form, which includes the "Experimental Subject's Bill of Rights."

I hereby agree to be a research participant in this research study:

_____ _____ _____

Research Participant's Signature Date Time

(For paper consent only, date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

**INDIVIDUAL OBTAINING CONSENT SIGNATURE**

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

**FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY**

NOTE: To determine who should sign below, review the guidance document, *Consenting Non English Speaking Research Participants (Pediatric or Adult) – Who Signs What?*

**Interpreter**: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

**FOR USE WHEN A WITNESS IS REQUIRED:**

**Witness**: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name

**COH IRB #21016 - Phase I Study of Escalating Doses of 90y-DOTA-Anti-CD25 Basiliximab Monoclonal Antibody Added to the Conditioning Regimen of Fludarabine, Melphalan and Organ Sparing Total Marrow and Lymphoid Irradiation (TMLI) as Conditioning for Allogeneic Hematopoietic Cell Transplantation in Patients with High-Risk Acute Leukemia, Myelodysplastic Syndrome, or non-Hodgkin's lymphoma**

## AUTHORIZATION TO USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI) FOR PURPOSES OF THIS STUDY:

**I.** **Purpose of this Authorization**: The information about your health is something that is protected by law and cannot, except for certain purposes, be disclosed (shared) without your permission. As part of this research, you are agreeing to allow City of Hope, its affiliated research doctors, healthcare providers, and physician network to use and share with others your protected health information ("PHI"), as needed for the research. If you agree to participate in the study named above (called the "Study"), you must sign this authorization in addition to the *Study Consent Form*.

**II.** **The Information About You that is Covered By this Authorization**: PHI refers to information that we maintain about you that identifies you and includes the information contained in your medical record. Your medical record consists of information related to your health and the treatment we provide to you, such as your medical history, the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures. If you sign this authorization, you are allowing City of Hope and the individuals indicated below to use and share any PHI we maintain about you that is required for your participation in the Study.

Certain information about you that is highly confidential is needed for the Study. If you sign this form, you are allowing City of Hope and the individuals indicated below to use and disclose the following highly confidential PHI about you: information about HIV/AIDS testing or treatment (including the fact that an HIV test was ordered, performed or reported, regardless of whether the results of such tests were positive or negative.

**III.** **Purposes for Uses and Sharing of your PHI; Who Will Use, Share and Receive your PHI**: Your PHI will be used and shared with others for the purpose of doing this research as described in the *Study Consent Form*. Your PHI will also be used to keep

the research sponsor informed about this Study, for reporting to those individuals and authorities responsible for overseeing our research activities to make sure that the activities are properly conducted, and to report to regulatory agencies as required by the Study.

The people authorized to use and share your PHI for purposes of the Study include the Principal Investigator and the research staff supporting the Study; your City of Hope physicians and the health care team; the Health Information Management Services Department (i.e., Medical Records Department), and affiliated research doctors and other medical centers participating in the research, if applicable. This also includes any agents or contractors used by these individuals or groups for purposes of conducting or managing this Study. At the City of Hope, the Institutional Review Board ("IRB"), and other City of Hope research regulatory committees will have access to your PHI as necessary to monitor research.

You are also allowing your PHI to be shared with the Office for Human Research Protections ("OHRP") and with any person or agency as required by law. In addition, certain other regulatory agencies, including, the Food and Drug Administration ("FDA") and the National Cancer Institute ("NCI").

Use and disclosure of your PHI may also continue for as long as the sponsor needs to maintain the PHI for purposes of obtaining approval of the treatment from the FDA or for other FDA reporting.

This authorization will allow us to use and share your PHI for the Study. No other additional uses and disclosures other than for the purposes of the Study is included in this authorization. City of Hope's Notice of Privacy Practices will continue to protect your non-Study information. If necessary, another separate permission will be obtained from you for any non-Study uses or sharing of your PHI.

**IV.** **<u>Expiration of this Authorization</u>**: This authorization to use and share your PHI will expire twenty-five (25) years from the date that you sign this authorization.

**V.** **<u>Further Sharing of Your PHI</u>**: Your privacy is important and this is the reason for having rules which control who can use or see your PHI. City of Hope maintains control over your PHI at present, but once we share this information with a third

party (for example, an individual or agency outside of the City of Hope), then it is no longer possible to maintain the same level of protection. The persons outside our control may not be governed by federal or state privacy laws and it is possible that they could share your PHI with others for whom you have not given permission.

The information from this Study may be published in scientific journals or presented at scientific meetings but your identity will be kept confidential.

**VI.** **<u>Your Rights Under this Authorization</u>**: You may cancel this permission to use and share your PHI at any time by contacting City of Hope's Privacy Officer at (626) 256-HOPE (4673) ext. 64025. You should ask for the form, *Revocation (Cancellation) of Authorization for Use of Protected Health Information for Research*. Fill this form out and return it as the form instructs. Your cancellation begins when the Health Information Management Department of City of Hope receives this form. If you cancel this authorization to use and share your PHI, you will no longer be able to participate in the Study. This is because the research under this Study cannot be conducted without your PHI.

Once you cancel your permission to use and share your PHI, the researchers and others involved in conducting the Study will no longer be able to use or share your PHI for this research. PHI already used and shared up to this point as part of this Study will continue to be used for purposes of this research. This means that any uses of your PHI and any PHI shared about you by City of Hope prior to receiving your cancellation (revocation) form cannot be taken back. While no further PHI about you will be shared for the Study, your PHI already shared will continue to be used in the overall Study.

Although you have the right to access medical and billing records that City of Hope maintains about you, this right will be temporarily suspended during the conduct of this Study to protect the integrity of the research. Your right to access these records will be reinstated upon the completion of this research.

**VII.** **<u>Signing this Authorization is Your Choice</u>:** Your ability to obtain care at the City of Hope will not be affected by your decision to sign this authorization form. You will be able to continue to receive health care at City of Hope if you choose not to sign this authorization form or if you sign this form and later cancel your permission to use and share your PHI.

If you agree to the use and sharing of your PHI, please sign below. You will be given a copy of this authorization form.

_____ _____ _____

Research Participant's Signature Date Time

(date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

**INDIVIDUAL OBTAINING CONSENT SIGNATURE**

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

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_____ _____ _____

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Print Interpreter's Name

**FOR USE WHEN A WITNESS IS REQUIRED:**

**Witness**: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name