Informed Consent to Participate in Research

BMT CTN 1903

Administration of HIV-specific T cells to HIV+ Patients Receiving High Dose Chemotherapy Followed by Autologous Stem Cell Rescue -Auto-RESIST

Your Name: _____

Principal Investigator:

Insert local PI information

Sponsor: This study is sponsored by the National Institutes of Health, through the Blood and Marrow Transplant Clinical Trials Network

The ethics of this study have been reviewed and approved by the National Marrow Donor Program Institutional Review Board.

Your study doctor or nurse will review this **Consent Form** with you, including:

- ✓ The purpose of the research
- ✓ Possible risks and benefits
- ✓ Other options available to you
- ✓ Your rights if you join the study

1. Study Overview

We invite you to join this clinical trial, also known as a research study. We're doing this study to see if it is possible to create and give you a type of cells called HST-NEETs to help your body fight HIV in the transplant setting. **HST-NEETs** are cells made when cells from your immune system are treated and grown in a lab. These cells are trained to target special proteins on your cells that are infected with HIV.

You're being asked to join because:

- You're taking **antiretroviral therapies** for HIV
- You have **lymphoma**
- You're getting an **autologous transplant**

If you join, you'll:

- Be in the study for 1 year.
- Get HST-NEETs. Before your transplant, your blood cells will be collected. Then, they're treated in a lab to create HST-NEETs. This takes about 6-7 weeks. You'll receive the HST-NEETs a few days after your transplant.
- After you get the HST-NEETs you will return for up to 8 additional study visits. Your blood will be drawn at these visits for assessments.

Some possible risks and benefits of joining the study include:

Possible Risks: The treatment may not work. And, you may have serious side effects.

Possible Benefits: The treatment may fight the HIV for some time. Also, doctors may learn about how to treat HIV better in future patients.

If you do **not** join the study, you have other treatment options, such as:

- Continue to get antiretroviral therapies to control HIV
- Receive standard treatment for lymphoma including the autologous transplant
- Joining another clinical trial. Talk to your doctor to see if there is a trial you can join.

Key points:

- Being in any research study is your choice.
- You may or may not benefit from being in the study. Knowledge gained from this study may help others.
- If you join the study, you can quit at any time. If you decide to quit the study, it will not affect your care at [name of facility or institution].

- Ask the study staff questions about anything you do not understand, or if you would like more information. You can ask questions now or any time.
- Take time to talk about the study with your doctor, study staff, and your family and friends. It is **your** choice to be in the study. If you decide to join, please sign the end of this Consent Form. You'll get a copy to keep. No one can force you to join this study.

2. Study Purpose

We're doing this study to see if a type of cells called HST-NEETs can help your body fight HIV. **HST-NEETs** are cells made from your own immune cells that have been treated and grown in a lab.

HST-NEETs have **not** been approved by the U.S. Food and Drug Administration (FDA) as a treatment for HIV. This study is registered with the FDA, and they will monitor it.

This is a phase 2 study. Studies in this phase test how well a new treatment will work to treat a disease.

3. Study Treatment and Tests

Before Your Treatment

You'll need to have several tests to see if you can be in the study. These tests are part of your regular care. They would be done even if you decide not to join this study. The tests include:

- Medical history and physical exam
- Blood and urine tests
- Tests to see how well your heart and lungs are working
- Tests to measure your lymphoma
- A pregnancy test (if you could be pregnant)

You will be asked to agree to an autologous bone marrow transplant and the BEAM Conditioning Regimen using your hospital's standard procedure. BEAM includes four medications which are a standard treatment used before transplants for lymphoma. The BEAM medications are Carmustine (BCNU), Cytarabine (Ara-C), Etoposide (VP-16) and Melphalan. You will be asked to sign a separate consent for the transplant and conditioning regimen, even if you do not participate in this study. Risks and details about the procedure are described in that consent form. If you do not agree to the autologous transplant you cannot be in this study testing HST-NEETS since we need to test HST-NEETS after you have had treatment with BEAM.

During the Study

If you join the study, here's what will happen: about 6 weeks before your transplant, you'll give about 8 tablespoons of blood via a routine blood draw. You will also give blood so doctors can measure the amount of HIV in your body. The blood will be sent to a lab to make the HST-NEETs cells. The HST-NEET cells will be given to you through your central venous catheter, like a blood transfusion, 3-7 days after the autologous transplant for your lymphoma

If it becomes clear that the lab cannot make the HST-NEETs with your cells supplied, additional blood samples may requested. Your doctor will notify you as soon as possible if this occurs. We will not delay your autologous transplant if the lab has trouble making the HST-NEETs.

After you get the HST-NEETs, you'll have up to 8 routine autologous transplant check-ups to test your health. The schedule of tests are listed in **Table 1**. Your participation will last for 1 year after your transplant.

Stopping treatment

We'll stop the treatment if:

- You don't meet the study requirements.
- You need a medical treatment not allowed in this study.
- You're too sick to safely get the HST-NEETs or transplant.
- You become pregnant.
- The study is stopped for any reason.

Table 1. Schedule of Study Tests for HST-NEET cells.

Tests	Pre-ASCT	Day 14	Day 21	Day 28	Day 35	Day 56	Day 100	Day 180	Day 365
Blood tests	X	X	X	X		X	X	X	X
Physical exam	X	X	X	X	X	X	X	X	X
Blood, Chemistry and Toxicity Tests for side effects				X	X	X	X	X	X
PET-CT or CT	X						X	X	X
Bone Marrow Biopsy for Pathology	X								

Seeing your Research Results

Your doctor may not share with you all of your research results. Your doctor will share any results with you if they show that you need new treatment or need to change your treatment. If you'd like to see specific results, tell your doctor.

Timeline and Participants

This study will include up to 12 participants, and will take about 4 years for all participants to complete.

4. Risks and Benefits

Possible Benefits

Doctors may learn more about how to treat HIV better. This could help people with HIV and lymphoma in the future.

Possible Risks

You may have side effects during the study. Side effects can range from mild to severe. Your health care team may give you medicine to help with certain side effects, like an upset stomach. In some cases, side effects can last a long time or may never go away. We don't expect that the HST-NEETs will have any effect on the lymphoma or the effectiveness of the autologous transplant, but don't know that for sure.

Risks of Medicines

Table 2. What it means for a side effect to be "likely", "less likely" and "rare, but serious"

Likely	This side effect is expected to happen in **more than** 20% of patients.
Less Likely	This side effect is expected to happen in 20% of patients **or fewer**.
Rare, but Serious	This side effect does not happen often – in **fewer than** 2% of patients – but is serious when it happens.

HST-NEETs

Likely (May happen in more than 20% of patients)	**Less Likely** (May happen in 20% or fewer patients, but more than 2%)	**Rare, but Serious** (May happen in 2% or fewer patients)
• None	• Chills or fever • Headache • High or low blood pressure • Muscle aches • Shortness of breath	• Risk of transmission of infections

Other Treatments or Medicines

Some medicines react with each other, so it's important to tell the study doctor or staff about any other drugs, treatments, or medicines you're taking. This includes non-prescription or over-the-counter medicines, vitamins, and herbal treatments.

It's also important that you tell the study staff about any changes to your medicines while you're in the study.

Reproductive Risks

The drugs used in autologous transplant are likely to affect your ability to have children. The HST-NEETs may also be associated with this risk. Doctors don't know all of the possible risks to your baby if you or your partner become pregnant during the study.

It is important that both men who are able to father a child and women who can become pregnant use birth control from the time of the blood draw to create the HST-NEETs until 6 months after transplant while on this study. Tell your doctor right away if you become pregnant or if your partner becomes pregnant during the study. Your doctor will talk with you about the risks to your unborn child and your options. If you become pregnant, you may be asked to leave the study.

Unforeseen Risks

There are some trials regarding T-cell infusions that have been associated with serious, sometimes life-threatening, problems. These problems have only been seen with genetically modified T-cells which are not being used in this approach; however, this is a new therapy and unanticipated side effects may occur.The study team will do everything they can to keep you safe and lower your risk of side effects.

For more information about risks and side effects, ask your study doctor.

5. Your Rights to Withdraw, Ask Questions, and Seek Other Treatment

Being in this study is your choice. You can choose **not** to be in this study or leave this study at any time. If you choose to not join or leave this study, it won't affect your regular medical care in any way. If at any time you are considering leaving the study, talk to your study doctor about your health and safety.

You have the right to ask questions about the study at any time. If you have questions about the study, please contact:

[Insert contact details for Principal Investigator or study team]

If you want to talk with someone not directly involved in the study, or have any complaints or questions about your rights as a research participant, you may contact:

NMDP Institutional Review Board Administrator at: 1 (800) 526-7809

You must tell [insert name of Principal Investigator] if you decide to leave the study.

If you choose not to join, other options are available. Your study doctor will talk with you about your options. If you decide not to join this study, your medical care will not be affected in any way. If you join this study, you cannot be in another clinical trial at the same time.

Your other choices may include:

- Continue to get antiretroviral therapies to control HIV
- Receive standard treatment for lymphoma
- Joining another clinical trial. Talk to your doctor to see if there is a trial you can join.

Every treatment option has benefits and risks. Talk with your doctor about your choices before you decide if you will be in this study.

6. New Information Available During the Study

During this study, the study doctors may learn new information about HST-NEETs or the risks and benefits of taking part in the study. If they learn new information, they'll tell you as soon as it's available.

The new information may mean that you can no longer participate in the study, or you may not want to continue. If this happens, the study doctor will stop your participation and offer you all available care to meet your health care needs.

7. Privacy, Confidentiality, and Use of Information

Your privacy is very important to us. The study doctors, study sponsor, and other groups with access to your study-related medical information will do everything they can to protect it. The study doctors can protect your records if there is a court case. However, some of your medical information may be shared if required by law. If this happens, the study doctors will do their best to make sure that any information that goes out to others will **not** identify you.

Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record is kept confidential (private). However, we cannot promise total privacy.

To make sure the study is running ethically, some government agencies or other groups may need to access part of your medical records. For this study, those groups include:

1. /Institution/
2. The Center for International Blood and Marrow Transplant Research (CIBMTR)

3. The National Marrow Donor Program (NMDP)
4. The Food and Drug Administration (FDA)
5. Office of Human Research Protection (OHRP)
6. The National Institutes of Health (NIH), which include the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI)
7. Data and Coordinating Center of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
8. The Cellular Therapy Laboratory (CTL) at Children's National Hospital (CNH)
9. Data and Safety Monitoring Board (DSMB), not part of /Institution/
10. Study investigators

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Study information may also be used for research in the future. These projects could be related to your disease or similar diseases, or development of the study drug.

We might use information from this study to get approval from the government, like the Food and Drug Administration (FDA).

Private information or blood taken during the study may be used for future research. If the study team does this, the information or blood will not be attached to you or your name in any way and results of the research done with it will not be given to you.

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

You will **not** be able to access your study results before the study is done. This helps keep the study results accurate and trustworthy.

When the study is complete, you can ask your study doctor for your health information from the study. **By signing this Consent Form, you agree to ask for your results only after the study is done.** You will still have access to your regular medical records.

Data about your health, including follow up after 1 year may be obtained by the BMT CTN from the CIBMTR, which captures information on all US transplants.

8. Leaving the Study

You can choose to leave the study at any time.

You may also be told to leave the study for reasons such as:

- You don't meet the study requirements.
- You need a medical treatment not allowed in this study.
- You're too sick to safely receive the HST-NEETs or transplant.
- You become pregnant.
- The study is stopped for any reason.

Even if you leave the study, the information already collected from you will be included in the study evaluation. If you don't want your information to be used, you **must** let your study doctor know.

9. Cost and Reimbursement

You will **not** be paid for joining this study. You will not be paid or reimbursed for any extra expenses (such as travel or meals) from your participation in this study.

A new drug or product may be developed from this study. [Institution] will **not** pay you if a commercial product is developed from blood or tissue taken from you during this study.

Most of the visits for this study are standard medical care for patients with lymphoma and will be billed to your health insurance company. You and/or your health insurance company will need to pay for some or all of the costs of standard medical treatment in this study. The costs of production and infusion of the HST NEETS and the extra blood draws will be covered by the study.

Some health insurance plans will not pay for costs of care when you take part in a research study. Check with your health plan or insurance company to find out if they will pay.

For questions about your costs, financial responsibilities, and/or health insurance coverage for this study, please contact [Center/ Financial Counselor] at: [Number].

Physical Injury as a Result of Participation

Tell your study doctor or staff if you think you've been hurt because of being in this study. You'll get medical treatment if you're hurt as a result of this study. You and/or your health insurance company will be charged for this treatment. The study sponsor will not pay for medical treatment as a result of unintended injury.

In case of injury resulting from this study, you don't lose any of your legal rights to seek payment by signing this form.

10. Health Insurance Portability and Accountability Act 1 (HIPAA) Authorization to use health information for research

Your local study hospital will give you a separate form with information about the Health Insurance Portability and Accountability Act 1 (HIPAA).

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- I have read and understood this Consent Form. The purpose and description of the research study has been explained to me.
- I have had the chance to ask questions, and understand the answers I have been given. I understand that I may ask questions at any time during the study.
- I freely agree to be a participant in the study.
- I have had the chance to discuss my participation in this research study with a family member or friend if I choose.
- I understand that…
    - I may not directly benefit from taking part in the study.
    - My name and personal information will not be identified even if information gained during the study is published.
    - I can leave this study at any time, and doing so will not affect my current care or prevent me from receiving future treatment.
    - I will be given a copy of this signed consent form.
    - I do not give up any legal rights by signing this form.

Participant Name (or Parent/Guardian)	Date (MM/DD/YYYY)
Participant Signature (or Parent/Guardian)	Date (MM/DD/YYYY)
Parent/Guardian Name	Date (MM/DD/YYYY)

Parent/Guardian Signature Date (MM/DD/YYYY)

Clinician certification

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

Clinician Name Date (MM/DD/YYYY)

Clinician Signature Date (MM/DD/YYYY)

Interpreter certification (if needed)

I certify that I have provided an accurate interpretation of this consent form. I believe the participant has understood the information provided.

Interpreter Name Date (MM/DD/YYYY)

Interpreter Signature Date (MM/DD/YYYY)