Assent to Participate in Research
(15 to 17 years of age)

BMT CTN 1903

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

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

Protocol: **BMT CTN 1903**

A. Why am I here?

We'd like you to join our study because you have HIV and you will receive an autologous transplant to treat your lymphoma. An autologous transplant destroys cancer cells in your blood and gives you your own blood-making cells back. Before your transplant, you will get chemotherapy (chemo) drugs to help your body prepare.

B. Why are you doing this study?

We want to know if it is possible to create and give you a type of cells called HST-NEETs to help your body fight HIV after transplant. 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.

C. What will happen to me?

We'll ask you to do a few things if you join the study. They are:

- Give about 8 tablespoons of blood or have the cells collected via apheresis, a procedure where blood is taken out of your body and put back into your body after the necessary parts are taken out. If the sample is collected through apheresis, you will be connected to a machine for 2 to 4 hours. The apheresis procedure will occur following your hospital's normal process. You will be monitored carefully during the procedure. If apheresis is needed, you will sign another consent for that procedure. We'll send the blood/cells to a lab to create the HST-NEETs cells before your transplant.
- Get HST-NEETs cells 3 to 7 days after transplant.

- Have 8 check-ups with the study doctors for at least 1 year.
- Give us permission to read your medical records and scans.
- Have tests done to find out more about your health.

We'll ask you how you're feeling. We'll also ask you how well you're able to do the things you normally do during the day.

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								

D. Will it hurt?

When we take your blood, it will hurt for a few seconds and the place where the needle went in might be a little red and sore. You might get a little bruise, but it goes away in a few days. If the manufacturing sample is collected through apheresis, it will hurt when the IV is placed in each arm. The procedure can take up to around 4 hours and you may bruise and be sore where the IVs are placed.

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

Apheresis

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	• Bleeding or other problems from the blood thinner • Low blood cell counts	• Infection

E. Will the study help me?

We don't know if the study will help you or not. It may lower the number of cells with HIV in your body. The information doctors learn from this study could also help future patients.

F. What if I have questions?

Your doctors and nurses will answer your questions. It's very important to us that you get all of your questions answered.

If you forget to ask a question but think of it later, you can call your doctor at [insert office number]. You can also ask your question the next time you see your doctor.

You can call the study office at [insert office number].

Be sure to get all of your questions answered.

G. Do I have to join this study?

You don't have to join this study. Tell your doctor and your parents or guardians if you don't want to be in the study. Your doctor won't be angry with you.

It's okay if you say yes now and change your mind and say no later.

You'll still be able to receive treatment for your lymphoma if you don't join this study.

Talk to your parents or guardians before you decide if you want to join this study. We'll also ask your parents if it's okay for you to join.

Writing your name on this page means that you agree to be in the study. Information learned about you during the study may be shared with you and your legal guardian. If you decide to quit the study, all you have to do is tell the person in charge.

You and your parent or guardian will get a copy of this form after you sign it.

Participant Name	Date (MM/DD/YYYY)
Participant Signature	
Researcher Name	Date (MM/DD/YYYY)
Researcher Signature	

Interpreter certification (if needed)

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

Interpreter Name	Date (MM/DD/YYYY)
Interpreter Signature	