

**Donor Assent to Participate in Research
(12 to 17 years of age)**

BMT CTN 2402

**Hematopoietic Cell Transplant and Gene Therapy for Non-
Malignant Blood Disorders Biobank Resource
(The 'HOPE Resource')**

Study Title: Hematopoietic Cell Transplant and Gene Therapy for Non-Malignant Blood Disorders Biobank Resource (HOPE Resource)

Protocol: BMT CTN 2402

Source of Support: National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (the NIH), Bethesda, Maryland

1. Why am I being asked to participate?

You're being asked to join this biospecimen and data collection (nontreatment) study because you are a bone marrow or stem cell donor for a relative who has a serious blood disorder that is being treated with a blood or marrow transplant (BMT).

2. What is this study about?

The goal of this study is to support future research in rare diseases and to help identify potential new treatments. To achieve this, we will collect samples from about 100 healthy related donors (like you) for patients undergoing transplant.

3. What will happen to me?

We'll ask you for a one-time collection of the following if you join the study:

- Blood (required);
- About 10 strands of your hair (optional); and/or
- About 10 nail clippings (optional)

4. 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.

There is a small risk of infection from the collection of nails and/or hair.

5. Will the study help me?

This study will not directly help you, but the information learned from this study may help others.

6. What if I have questions?

The treatment team will answer your questions. It's important that you get all of your questions answered.

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

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

Be sure to get all of your questions answered.

7. Sample Information

Here's what you need to know about your samples:

- Your samples will not have your name on them. They will not be linked to you. The research results will not be shared with you.
- Your samples will be stored in a safe place called a repository. Other researchers can use them for approved studies.
- Your blood and cells have something called DNA. DNA is like instructions that tell your body how to grow and work. It includes things like hair and eye color and how your body fights infections. Sometimes DNA has changes called mutations. Scientists may study your DNA to learn why some people do better after transplant or gene therapy and why some have problems.
- Scientists may use a method called GWAS (Genome-Wide Association Study). This looks at many genes to find changes that might cause disease or affect transplant results. Your samples or your donor's samples may be used for this, but your name will never be linked to the results.
- If your samples are used in these studies, the results will go into a public research database called the NIH Genotype and Phenotype Database. This database will not have your name or anything that can identify you.
- There is a law called the Genetic Information Nondiscrimination Act (GINA). It says health insurance companies and most employers cannot use your genetic information to

treat you unfairly. This law does not cover life insurance, disability insurance, or long-term care insurance.

- Your samples will be kept until they are used up or no longer needed. Then they will be destroyed.
- If you change your mind later and want your samples destroyed, you can contact [insert contact info]. We will try to remove and destroy them, but sometimes we cannot. For example, if your samples have already been used in research, that information cannot be taken back.

8. Do I have to join this study?

It's your choice to participate in the study. Even if you say 'no' to giving samples for this research study, the patient can still receive a transplant from you. If you agree to participate, collection of research samples will be prior to collection of your bone marrow or stem cell (Hematopoietic cell) donation.

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

Optional Samples

Giving other samples (like hair or nails) is my choice. These samples will also have your name removed and stored for research. You can say "YES" or "NO" for each sample by checking the box.

Skin, Hair, and Nails

Why: All your cells have DNA, which is like instructions for how your body works. Sometimes DNA changes as you grow. By looking at things like hair and nails, researchers can tell if these changes happened before you were born or later in life. For related donors, DNA samples from different parts of the body are important because they help scientists figure out if changes are inherited from family or developed as you got older. This information can help doctors decide if a donor is a good match and can give scientists clues about family health risks.

Hair Plucks (10–15 hairs)

How: We gently pull out a few hairs with the root. You can do this yourself or have a grown-up or research helper do it. This takes about 5 minutes.

☐ **YES** – I agree to give hair samples for research

☐ **NO** – I do not agree to give hair samples for research

Nail Clippings (8–10 nails)

How: We clip some nails with regular nail clippers. You can do this yourself or have a grown-up or helper do it. This takes about 5 minutes.

- ☐ **YES** – I agree to give nail samples for research
- ☐ **NO** – I do not agree to give nail samples for research

Writing your name on this page means that you agree to be in the study. 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.

Signature of Participant

Date (MM/DD/YYYY)

Printed Name of Participant

Signature of Researcher

Date (MM/DD/YYYY)

Printed Name of Researcher