

Donor Assent to Participate in Research (7 to 11 years of age)

BMT CTN 2402

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

Participant's
Name: _____

Date: _____

Dr (s). [insert Dr (s) names here] is/are studying serious blood problems.

We are asking for your help because we want to learn more about people with serious blood disorders and you are a bone marrow or stem cell donor for someone you are related to. We will enroll about 100 donors like you.

If you agree to be in this study, we will ask you to give some of these samples one time before the collection of your bone marrow or stem cells for your family member:

- Blood, usually from your arm;
- About 10 strands of your hair; and/or
- About 10 nail clippings

When you are in a study, sometimes good things and bad things can happen. These things may or may not happen to you.

Here are the bad things that can happen:

- When you give blood, it might hurt a little bit, and you might get a bruise. But we will only take blood one time for the study.
- You might get an infection from giving nail clippings or hair, but this is unlikely.

Here are the good things that can happen:

- This study may not help you at this time, but you can help doctors learn about ways to help other kids that have blood disorders.

You do not have to be in this study if you do not want to. Even if you say 'no' to giving samples for this study, your family member can still receive a transplant from you. If you say 'yes' and change your mind, you may stop being in this study at any time. Remember, being in this study is up to you.

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, and the results will not be shared with you.
- Your samples will be kept in a safe place called a repository. Other scientists can use them for approved research studies.
- Your blood and cells have something called DNA. DNA is like a special code or blueprint that tells your body how to grow and work. It includes things like your hair and eye color and how your body fights sickness. 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.
- Your samples will be kept until they are used up or not needed anymore. 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.

Talk with your grown-ups before you decide. We will also ask your grown-ups if you can be in this study. But even if they say “yes,” **you** can still say no.

You can ask any questions that you have. If you have questions later, your grown-ups can call your doctor.

[insert number (s) here]

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.

Hair and Nails

Why: All your cells have something called DNA, which is like instructions that tell your body how to grow and work. Sometimes DNA changes as you grow. By looking at things like your hair and nails, researchers can see if these changes happened before you were born or later in life. For family members who are donors, looking at DNA in different parts of the body is important. It helps scientists know if changes were inherited from family or happened during life. This information can help doctors decide if someone is a good donor and can also teach scientists more about family health risks.

Hair Plucks (10–15 hairs)

How: We will gently pull out a few hairs with the root. You can do this yourself, or you can ask a grown-up or a research helper to do it for you. This will only take 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 researcher 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

Sign and write your name on the line below if you want to be in this study. You can also tell us if you want to give extra blood to help. Remember, you can change your mind at any time. You can keep a copy of this form at home.

Minor Assent

Signature of Participant

Date (MM/DD/YYYY)

Printed Name of Participant

Signature of Researcher

Date (MM/DD/YYYY)

Printed Name of Researcher