

**Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular
Therapies and Marrow Toxic Injuries**

**Adult Research Consent Form and Parent/Legal Guardian Permission Form
Allogeneic or Autologous Recipient
SARS-CoV-2 Vaccine Response Study**

The word “you” throughout this form refers to you or your child.

1. Research Overview

You are being invited to be in a research project with the CIBMTR. The research project is about how well the SARS-CoV-2 (COVID-19) vaccine works following transplant or CAR-T cell therapy. Your blood has genetic information, called DNA. We ask for your permission to collect and store your blood and DNA for this research and for future research.

We’re asking you to participate because you are receiving the SARS-CoV-2 vaccine after being treated with transplant or CAR-T cell therapy.

In addition to testing your blood samples for antibodies to the SARS-CoV-2 (COVID-19) virus, researchers may use your samples to learn more about:

- Other immune responses to the vaccine, like the production of anti-virus T-cells
- What affects transplant and cell therapy results
- Diseases treated by transplant and cell therapy

2. What to Expect

If you agree to give blood samples, here’s what will happen:

- Your doctor will collect a small sample of your blood (up to 3.3 tablespoons) at five or six total timepoints (depending on your vaccine dose schedule) before and after receiving the SARS-CoV-2 vaccine.
 - Pre-vaccine dose #1
 - Two to five weeks after vaccine dose #1 or just before vaccine dose #2 for two-dose vaccines
 - Four to eight weeks after vaccine dose #2 or similar time frame for single dose vaccines or Pre-vaccine dose #3 if given within eight weeks of vaccine dose #2

- Pre-vaccine dose #3, if given. Only collected if dose #3 is delayed more than eight weeks after vaccine dose #2
 - One to five weeks after vaccine dose #3, if given
 - 7-9 months after first vaccine dose
- Your blood and DNA will be stored. Your name will **not** be on the containers.
- We will keep the samples at the **Research Sample Repository**. A repository - like a warehouse - is a place that protects, stores and sends out samples for research studies. The research studies must be approved by a group of scientists. Your samples may be stored and used for months, years or decades.
- Your blood cells may be grown in a lab for approved research studies. Your research samples will be stored at the Repository until they are used up.

The DNA testing may include “whole genome sequencing”. Every cell in your body contains the genetic code for your DNA. Whole genome sequencing looks at the entire genome, or genetic code. All people have about 99.6% identical genomes. However, everyone is unique, and between any two people there could be about 24 million places where the “spelling” of the code is different. Linking these differences in spelling (gene variants) with differences in BMT or cellular therapy outcomes may help us to understand how these variants are related to disease and treatment success.

3. Your Right to Leave or Not Join the Repository

If you agree to be in this research study, you can change your mind at any time. If you change your mind, please email or write to [name of TC coordinator/team]. See page [#] for contact information.

If you change your mind, we will destroy any unused samples.

If you choose not to participate in this study, there will be no change in your care. Your decision will not affect your relationship with your doctor, treatment center or the CIBMTR.

4. Risks and Benefits

You will receive the results of the SARS-CoV-2 (COVID-19) virus antibody testing from your local study team following completion of your participation on this research study. You should discuss the results with your doctor. It is unknown whether a high or low antibody level affects your risk of infection with COVID-19. Regardless of the level, you

should continue to practice all safety measures recommended by the US Center for Disease Control (CDC) and your doctor. You will not benefit from any future research done on your blood sample. The future research done on your blood samples may help future patients who need a transplant or cellular therapy.

There are no major risks with blood draws. A blood draw can hurt a little and may cause a bruise. In rare cases, people feel lightheaded or faint. Only trained people will draw your blood.

Since your DNA is unique to you, there is a small risk that someone could trace your samples back to you. Researchers accessing your information will do their best to protect your privacy and to keep your information confidential. We will **not** give information that could identify you to researchers, publish it or present it at scientific meetings.

5. Privacy, Confidentiality and Use of Information

Your privacy is important to us. We will make every effort to protect it.

Your blood samples will be stored with a bar code. The Repository staff and future researchers do not have a link to this code. However, a link does exist. The link is stored at [insert center name here].

To expand research, it is helpful for researchers to share information. They do this by putting the information into one or more research databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease.

If you agree to take part in the study, some of your genetic and health information may be stored in a research database, such as the Genotype and Phenotype Database maintained by the National Institutes of Health (NIH). Researchers with an approved study may be able to see and use your information. Your name and other information that can identify you will never be put into the database. The CIBMTR restricts the use of the data to studies of BMT and cellular therapy.

A description of this clinical study is available on <http://www.ClinicalTrials.gov>, Identifier: NCT04920474, 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 receive any results generated from this research.

This research is covered by a Certificate of Confidentiality from the Health Resources and Services Administration (HRSA). Researchers can protect your information if there is a court case. However, some of your medical information may be shared if required by law. If this happens, the researchers will do their best to make sure that any information that goes out to others will **not** identify you.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and employers with 15 or more people to discriminate against you based on your genetic information. Health insurance companies and group health plans may **not** request your genetic information or use it to make decisions about your health insurance. This federal law will **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

The results of research done with your blood, tissue and DNA may be seen or used by:

- Center for International Blood & Marrow Transplant Research (CIBMTR)
- Health Resources and Services Administration (HRSA)
- Food and Drug Administration (FDA)
- U.S. government agency sponsor

The results of the SARS-CoV-2 (COVID-19) virus antibody testing will be provided to your local study team and may be shared with you following completion of your participation on this study. The results of any additional future research done on your blood, tissue and DNA will **not** be shared with you.

6. Cost and Reimbursement

You will not be paid for taking part in this research study. It will not cost you anything to take part in this research. The CIBMTR may sell your blood sample to other organizations such as drug companies. Samples that are sold or shared outside the CIBMTR never include any information that could identify you. The organization may use your blood sample to make products or therapies that benefit patients or are valuable to researchers. You will not receive any money or other benefit from any products or therapies that are developed from your blood sample.

Physical Injury as a Result of Participation

Tell your treatment center coordinator if you think you've been hurt because of joining this research study:

[Name]

[Contact details]

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. This study will **not** pay for medical treatment as a result of unintended injury. If you're injured, you do **not** lose any of your legal rights to seek payment by signing this form.

7. For More Information

If you'd like more information about the Repository, contact:

[Name]

[Contact details]

For more information about your rights, please contact:

NMDP IRB Administrator

Call: 1 (800) 526-7809

If you wish to speak to someone **not** directly involved in the study, you may contact a **BMT Patient Navigator** in the Be The Match® Patient Support Center:

Call: 1 (888) 999-6743

Email: patientinfo@nmdp.org

You will get a copy of this consent form for your records.

8. Statement of Consent to Participate in the Research Sample Repository

- I have read and understood this Consent Form. The purpose and description of the Repository 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.
- I freely agree to participate in the Repository.

- I understand that:
 - I will not benefit from being in the Repository.
 - My name and personal information will not be identified.
 - I can leave the Repository at any time and doing so will not affect my health care.
 - My study team will receive results of the SARS-CoV-2 (COVID-19) virus antibody testing done on my sample and may share with me.
 - I will not receive any results related to future testing on my sample.
 - I will get a copy of this signed consent form.
 - I do not give up any legal rights by signing this form.

Recipient/Subject Signature (if 18 years or older)

Date (MM/DD/YYYY)

Print Name of Recipient/Subject

Parent/Legal Guardian Signature
(if recipient/subject is <18 years old)

Date (MM/DD/YYYY)

Print Name of Parent/Legal Guardian

Certification of Healthcare Professional

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.

Healthcare Professional Name

Date (MM/DD/YYYY)

Healthcare Professional Signature

Date (MM/DD/YYYY)

Interpreter Certification

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)

An oral translation of this document was administered to the subject in _____
(state language) by an individual proficient in English and _____
(state language). See the attached short form addendum for documentation.