# Patient Information Leaflet for the EBMT Registry 12-17 yr

Dear boy/girl,

You have been given this leaflet because you are receiving a blood or bone marrow transplantation, immune effector cell (IEC) therapy and/or a treatment that affects your immune system.

EBMT is a not for profit organisation that through research tries to improve the lives of patients with blood-related disorders. With this letter we would like to ask you if we can collect your clinical and personal data and keep it in our database (EBMT Registry).

* Personal data = information on who you are, for instance your birth date and gender.
* Clinical data = (also a kind of personal data) information on your health and treatment, for instance if you are sick and if you use medicines.

The clinical data we collect can be used in scientific research to determine the safety and efficacy of the treatments you receive. The goal of the Registry is to help save the lives of patients with blood cancers and other life-threatening diseases.

In this leaflet, we would like to give you all information you may need to decide if you want to share your data. You are free to decide whether or not you agree to share your data with the EBMT Registry. Please read this information leaflet carefully. Take as much time as you need before you decide.

If you want to share your data, you can sign the form at end of this leaflet. We also need a signature of your parents. You can always stop sharing your data. Just tell your parents and doctor. Please ask your parents or your doctor if you have any questions. You can also read the leaflet that was given to your parents.

# Why are you asking me?

We ask you to share your data with the EBMT Registry because you

* are or will be involved in blood or bone marrow transplantation and/or;
* are diagnosed with bone marrow failures and receive treatment that has effect on your immune system and/or;
* receive immune effector cell (IEC)therapy.

# What will happen to you if you decide to share your data with the Registry?

For you, nothing will change. You will visit the hospital as needed for your treatment. No tests will be needed for this Registry.

# What will happen to your data in the EBMT Registry?

## What data is being collected and processed?

During the normal visits the doctor will give us information (personal data) on:

* you, like initials, date/year of birth, your gender and the country you live in
* your disease
* your medical condition during the visits
* your treatment
* your body’s response to the treatment.

To protect your privacy, we link your personal data to a unique number. There will be a “key” which is needed to link your data with the number. This “key” will stay in the hospital. When communicating about your personal data we will only use this number. This helps us to use your personal data without the direct risk of identifying you. However, we may need to send some minimal personal data to others. This data alone will never lead to you directly.

## What is the purpose of collecting and processing your data?

The EBMT Registry will function as a place where researchers, health authorities, and other partners such as pharmaceutical companies can collect data from. They might do this to improve knowledge, patient care and outcome of different therapies that affect your immune system. Therefore, we also ask you to allow us to share your personal data with these possible partners.

## How long will your data be stored?

We will keep your data indefinitely so that it can be used in the future for scientific research purposes.

The partners to whom we will send your data, will keep your data as long as it has purpose for the goal described above under 3.2.

## Who has access to your data in the EBMT Registry?

Only persons working at EBMT and your hospital will be able to access your data in the EBMT Registry. Access to others may be given for purposes as described in 3.2.

## Who has access to your medical records?

The hospital personnel will copy the information from your medical records to the EBMT Registry. EBMT employees and possibly regulatory authorities, may need to access your medical records at your hospital. This is needed to check if all information is accurate and according to current regulations.

The persons that will have access to your medical records will also see the information that will directly identify you. These persons will keep your information a secret. We ask you to allow this access to your medical records for the purpose described.

## Who is responsible for your data?

Together with your hospital, we are responsible for the protection of the data in the Registry. A possible partner will specify the data they need and the goal for which they need the data. This partner will then be responsible for the protection of the data they receive for the specified purpose.

In the European Union, the law (GDPR) instructs people how data should be protected. Partners may be in the European Union, but also in countries outside of the European Union. We will make sure that your data will be kept a secret no matter where your data will be sent to.

## What are your rights?

We ask you to agree to your personal data being accessed, stored and processed. If you do not agree, then your data will not be sent to the EBMT Registry or to any of our partners.

If you do agree, the data in the EBMT Registry will continue to be in your control. You can ask a copy of the information that is in the Registry and ask for a correction if anything is not correct.

If you agree you can always stop sharing your data in the future. You can then ask that your personal data be erased from the EBMT Registry database and from other databases to which your data may have been sent. This will not affect the treatment you receive.

# Who can you contact?

If you would like more information you can ask your parents or doctor. For questions on the protection of your data you can also contact:

[INSERT HOSPITAL DPO]

[NAME, TITLE] [CONTACT DETAILS]

Registry Holder [EBMT]

EBMT Data Protection Officer E-mail: data.protection@ebmt.org

# EBMT REGISTRY INFORMED ASSENT/CO-CONSENT FORM

* I have read and understood the Patient Information Leaflet for Adolescents (version 1.0, 26/07/2024). I had the opportunity to ask questions. My questions have been answered.
* I have had enough time to decide if I want to share my data with the EBMT Registry.
* I know I do not HAVE to participate. I can always quit when I want to. I do not have to give a reason. My medical treatment will not be affected.
* I agree that my information is shared as specified by my parents in their consent.

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| --- |
| **I would like to share my data with the EBMT**   |

Name of the patient

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

If information becomes available during the period that data is stored in the Registry which may influence the consent of the patient, the hospital will inform him/her in time.

Name of hospital representative:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

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Additional information has been provided by (when applicable):

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position/title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_ / \_\_\_ / \_\_\_\_\_\_

*Copies to be signed: 1 for the patient, 1 to be stored by the hospital.*