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Donor Information Leaflet for the EBMT Registry

Dear Madam/Sir,

You have been given this leaflet because you are a donor of stem cells (from blood or bone marrow), or of leukocytes for immune effector cell therapy. We would like to invite you to share your data with the Registry (database) of the European Society for Blood and Marrow Transplantation (EBMT).

The EBMT is a not-for-profit organisation that consists of hospitals and professionals working in the field of clinical bone marrow transplantation and immune effector cell therapy. The EBMT maintains an international patient/donor database known as the EBMT Registry. The Registry contains patients and donor clinical data that is used in scientific research and assessments of the safety and efficacy of the procedures you receive. The goal of the Registry is to save the lives of patients with blood cancers and other life-threatening diseases.

In this leaflet, we would like to explain why we are asking you to share your data with the EBMT Registry; what the purpose of data processing is; which data is being collected; how your data is being protected and what your rights are. You are free to decide whether or not to share your data with the EBMT Registry. Please read this information leaflet carefully and discuss it with your partner, family or friends. Take as much time as you need to think about sharing your data.

If, after reading the information, you agree to take part, you will be asked to sign and date two copies of the consent form. You will be given one copy to keep and the other copy will remain in your donor file at the hospital/donation centre. If you decide not to share your data or to withdraw at a later date, this will not affect the type or quality of treatment you receive. Please ask at the donor registry/donation centre if anything is not clear or if you would like some more information.

If you are giving consent on behalf of a child in your care, please explain to the child as much as they can understand.

Summary

Registry of the European Society for Blood and Marrow Transplantation (EBMT)

Aim of the Registry

The main function of the Registry is to collect clinical data for research and to enhance the safety and effectiveness of treatments and the quality of care. The ultimate goal is to save the lives of patients with blood cancers and other life-threatening diseases.

You can find the information of all EBMT studies in which your personal data might be used, by visiting our website on the following page: <https://www.ebmt.org/research/studies>

The EBMT works with many “Collaboration Partners” internationally, including national registries, national health authorities, and researchers from scientific/clinical institutions. Therefore, we also request your consent to share your personal data with these EBMT partners to fulfil the purpose described above.

For the purposes described in section 1.2, the EBMT may also work with the European Medicines Agency (EMA; www.ema.europa.eu/ema), national health authorities, Health Technology Assessment bodies, and the marketing authorisation holders (MAHs; the pharmaceutical companies owning the therapies that patients like you are receiving).

Who is invited to share data with the EBMT?

Donors of stem cells (from blood or bone marrow), or of leukocytes for immune effector cell therapy are invited to share their data.

What will happen if you agree to share your data with the EBMT?

If you decide to share your data, medical and donation data, will be collected. Some of these data will be collected from your routine donation visits. For medical follow-up checks you will not need to visit the hospital/donation centre specifically for this purpose. These checks can also be done at your general practitioner and be sent to the hospital/donation centre.

What will happen to your personal data?

All your data will remain confidential and will be stored in a certified and secure database of the European Society for Blood and Marrow Transplantation (EBMT). All data processing activities will comply with the European General Data Protection Regulation (2016/679) and applicable local laws.

Who should you contact in case you have questions?

At your institute:

Name:

Position/Title:

Address:

Phone number:

At the EBMT:

EBMT Data Protection Officer

E-mail: data.protection@ebmt.org

Phone number: +34 93 453 8570

1. What will happen to your personal data in the EBMT Registry?

1.1 What data is being collected and processed?

According to the European General Data Protection Regulation (GDPR (2016/679)), personal data is defined as any information that relates to an identified or identifiable living individual. For the purpose of the EBMT Registry, the following information from your medical records will be processed:

- Initials, date/year of birth, gender, unique patient/donor number given by your hospital/donation centre and country
- Medical history, physical examination, and results from blood and if applicable bone marrow examinations
- Transfusions, medication
- Complications during stem cell mobilisation and donation

Personal data that is stored in the EBMT Registry will be linked to your initials, date/year of birth, gender and unique patient/donor number given by the hospital/donation centre. These minimal identifiable data items are necessary to ensure that data collected at different times is accurately stored in the same record. They will not be used to identify you as an individual.

To protect your privacy, your data is given a unique and non-informative database number. This process is known as 'pseudonymisation' and is defined in the GDPR. It allows your personal data to be processed in such a way that the data can no longer be linked back to you without the use of additional data which is stored at your local hospital. The EBMT is committed to minimising the sharing of personal data, particularly minimal identifiable patient data. Whenever possible, the EBMT shares pseudonymised data or, when circumstances allow, anonymised data. However, in certain situations, for example to prevent the duplication of data, the minimal identifiable data may still need to be shared, but this will always be done under legally required data protection measures.

1.2 How is the data stored in the EBMT Registry?

The data is stored in an electronic, certified, secure database of the EBMT and is subject to the European data protection regulations. This database is located in a country that is part of the European Union, and is under a stringent access control policy.

1.3 How long will the data be stored?

The EBMT will hold your data indefinitely so that it can be used in the future for scientific research purposes.

Collaboration Partners will hold your personal data for as long as it serves the purposes described above in section **Error! Reference source not found.**

1.4 Who has access to the data in the EBMT Registry?

Access to the data in the EBMT Registry will be limited to EBMT research staff and authorised staff members at your hospital. Upon request from your hospital/donation centre, access may be granted to your national registries in the field of blood and/or bone marrow transplantation and IEC therapy and/or your disease.

1.5 Who has access to your donor files?

Access to data from your medical records may be needed to verify that the data collection for the EBMT Registry is done accurately and in compliance with current regulations. Access to your hospital/donor centre medical records will be restricted to:

- the staff at your hospital
- a monitor or auditor who has been commissioned by the EBMT
- regulatory health authorities

All parties have a duty of confidentiality to you as a research participant. We request your consent to allow the above-mentioned access to your medical records for this purpose.

1.6 Will the data in the EBMT Registry be shared with any third parties?

With your consent, your personal data in the EBMT Registry may be shared with the Collaboration Partners for the purposes described above in section 1.1. As part of such collaborations, your anonymized personal data may be sent to countries outside of those covered by the GDPR (2016/679). The EBMT arranges GDPR-required safeguards to protect your personal data where it is sent to so-called third countries outside of the European Union that have not been recognised by the European Commission as providing an equivalent level of data protection.

1.7 What is the legal basis for processing the data and who is responsible?

The GDPR (2016/679) regulates the collection, storage and processing of personal data. The purpose of the regulation is to guarantee your privacy. To comply with these regulations, we ask you to give consent as the legal basis for the collection, processing and storage of your personal data in the EBMT Registry for the purposes described in section **Error! Reference source not found.** **Error! Reference source not found.**

The EBMT and your hospital are joint 'controllers' of your personal data in the EBMT Registry. This means that they both determine the purpose of data processing (why) and the means of processing (how). Both the EBMT and your hospital are responsible for the protection of the data in the Registry.

In the event that your data in the EBMT Registry is shared with health authorities, HTA bodies, MAHs or other scientific/clinical collaboration partners for the purposes described above in section 1.1, these partners will also be a controller of your personal data for that specific purpose and therefore also be responsible for the protection of the data.

1.8 What are your rights (as a data subject)?

You are being asked to consent to your personal data being accessed, stored and processed. If you withhold consent, then your data will not be sent to the EBMT or to any of our collaborators and will not be used for the purposes of research to help future donors and patients.

If you give consent, the data held by the EBMT will continue to be in your control. You have the right to request access to and/or rectification of your personal data or to file a complaint with the national data protection authority. You also have the right to withdraw your consent at any time in the future. Further, you have the right to request that your personal data be erased from the EBMT Registry database and from other databases to which your data may have been exported. This will not affect the type or quality of treatment you receive.

Children and adolescents also have the right to withdraw consent when they come of legal age.



1.9 Are there any extra costs involved if you decide to share your data with the Registry?

No extra costs are involved related to sharing your data and nor will you receive any payment for sharing your data with the Registry.

2. Who should you contact for more information or if you wish to exercise your rights?

For more information or if you wish to exercise any of your rights listed in section 1.8, please contact:

[INSERT HOSPITAL DPO]

[NAME, TITLE]

[CONTACT DETAILS]

Registry Holder [EBMT]

EBMT Data Protection Officer

E-mail: data.protection@ebmt.org

Phone number: +34 93 453 8570



EBMT REGISTRY INFORMED CONSENT FORM

I have read the Donor Information Leaflet (version 1.2), had the opportunity to ask questions and received satisfactory answers. I have had an appropriate amount of time to decide if I want to share my data with the EBMT Registry. I understand that participation is completely voluntary and I am free to withdraw at any time, without giving a reason, without my medical care or legal rights being affected.

By signing this Consent Form, I acknowledge that:

- | | Yes | No |
|---|--------------------------|--------------------------|
| 1. I consent to my personal data, including minimal identifiable data as defined in section 1.1, being reported to and processed by the EBMT Registry and that my data will be kept indefinitely. | <input type="checkbox"/> | <input type="checkbox"/> |

In addition to the above,

- | | | |
|--|--------------------------|--------------------------|
| 2. I consent to my personal data, including minimal identifiable data, in the EBMT Registry being shared with health authorities and researchers across scientific or clinical institutions, provided that an adequate level of protection for my privacy is applied or that sufficient contractual safeguards are arranged if this data is to be sent outside the European Economic Area. | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I consent to my pseudonymised data in the EBMT Registry being shared with national health authorities and HTA bodies/reimbursement agencies, provided that an adequate level of protection for my privacy is applied or that sufficient contractual safeguards are arranged if my pseudonymised data is being shared outside the European Economic Area. | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I give permission to monitors and auditors from the EBMT and regulatory authorities to review my medical records in accordance with applicable laws and under full confidentiality. | <input type="checkbox"/> | <input type="checkbox"/> |



Consent form for sharing data with EBMT and EBMT collaboration partners

Name of the donor / Name of donor's legal representative:

Signature: _____ Date: ___ / ___ / _____

Name of the witness (if applicable): _____

Signature: _____ Date: ___ / ___ / _____

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

Name of hospital representative: _____

Signature: _____ Date: ___ / ___ / _____

Additional information has been provided by (when applicable):

Name: _____

Position/title: _____

Signature: _____ Date: ___ / ___ / _____

Copies to be signed: 1 for the donor, 1 to be stored by the hospital, 1 for the legal representative/impartial witness (delete if not applicable).