

Name of Document: EBMT-F-007-01-Consent Form For Data Registration With EBMT Approved by: EBMT Executive Committee Author: Data Protection Coordinator	Creation date: 07/02/2018 Effective date: 07/05/2018 Review date: n/a Modification: n/a	
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Consent Form For Data Registration With EBMT

The European Society for Blood and Marrow Transplantation (EBMT) maintains an international patient database known as the EBMT Registry. The Registry goes back to the beginning of the 1970's and contains patient clinical data including aspects of the diagnosis, first line treatments, immunosuppressive treatments, haematopoietic stem cell transplant (HSCT) or cell therapy associated procedures, complications and outcome.

The purpose of this Registry is to collect data that will be used for research in our field, to provide a reference of treatment results that centres can use for quality controls (a process named benchmarking), for the development of new and improved transplant, cell therapy and immunosuppression procedures, and to improve the quality of these procedures through the accreditation of treatment units.

The data is stored in an electronic database located in a European country and is subject to the regulations of the General Data Protection Regulation (GDPR) issued by the European Union. Only European countries that follow this regulation, regardless of whether they are members of the European Union or not can host the data. The database is protected by safeguards that ensure security, including compliance with NEN7510/ISO27001 certification and a stringent access control policy.

The EBMT works in partnership with local healthcare providers to collect data on patients. Personal data is limited to your initials, date of birth, and gender. These items are necessary in order to ensure that data collected at different times is accurately stored in the same record. It is not used and cannot be used for identification of the individual. This process is known as pseudonymisation and is defined in the GDPR regulations. Each patient's report is given a unique and non-informative database number which is the one used for research purposes. Nobody outside the hospital where you are treated will be able to identify you as an individual from the data stored. Your data will add to the effectiveness of the Registry, and therefore contribute to improvements in patient care and outcome.

To fulfil the purpose of the Registry described above, the EBMT works through international collaborations with many partners, including researchers across scientific or clinical institutions, the European Medicines Agency (EMA; www.ema.europa.eu/ema), pharmaceutical industry and other institutions and healthcare providers. As part of such collaborations, your pseudonymised data may be sent outside of countries covered by the European Union GDPR. Patient data sent outside this area in the context of EBMT research projects will be identified by the non-informative database number, and personal items such as date of birth, initials or the unique patient number (UPN) used by the hospital to trace your medical records will not be exported.

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In addition to the EBMT, the hospital where you are being treated is currently sharing data with the following institutions through the EBMT (Note: this is for the centre to complete as applicable, describing the institution/s and purpose of this data sharing; e.g. national HCT societies):

Institution number 1

Institution number 2

Institution number 3

The European Union GDPR (<https://www.eugdpr.org/>) regulates the collection and storage of personal data.

The purpose of the regulation is to guarantee your privacy as a patient contributing data to scientific research. To comply with these regulation, you need to give consent to collection and storage of the personal data we indicated above before data can be shared with any institution. With your permission, the EBMT and other institutions you have given consent for, will hold your data indefinitely so that it can be used to compare with other patient data in the future. If you are giving consent on behalf of a child in your care, please explain to the child as much as they can understand.

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 patients.

If you give consent, the data held by the EBMT will continue to be in your control. You have the right to see that data and to request any corrections to it. You also have the right to withdraw consent whenever you choose in the future, your wishes will be respected, and your personal data will no longer be made available for future research. You also have the right to request that your personal data be completely erased from the EBMT Registry database and from databases to which your data has been exported. Children and young people also have the right to withdraw consent when they come of legal age. There are procedures to follow that you can find on the EBMT website (www.ebmt.org/consent), by contacting your treatment centre or by emailing data.protection@ebmt.org.

If you agree for your data to be sent to the EBMT, please, complete the form below to give your consent to the collection of data concerning your illness and treatment, and to the reporting of these data to the EBMT Registry. Please, check the boxes to indicate your consent. Should you have any questions about this consent please ask your doctor or go to the EBMT website (www.ebmt.org/consent).

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I (Patient)

I (Parent, Guardian, as per national regulations)

have been informed to my satisfaction regarding data collection and reporting to the EBMT and

☐ consent to minimal identifiable data on my treatment being reported to the Registry run by the EBMT.

☐ consent to minimal identifiable data on my treatment being reported through the EBMT to

Institution	Consent given (*delete as applicable)
1. [for the centre to complete describing the institution (e.g.: national registry) and objective of the data sharing]	Yes/ No*
2. [as above]	Yes/ No*
3. [as above]	Yes/ No*

☐ consent to pseudonymised data being sent to scientific or clinical institutions in addition or the same as any listed above that are situated outside the European Economic Area and to their use in EBMT studies conducted outside of the European Union provided the same level of protection for my privacy is applied.

If consenting on behalf of a child, please provide as well:

- Name of Child
- Date the child will reach age of consent:
- Signature of child (if appropriate)

Date: Signed:

Witness name (if applicable):

Date: Signed:

Consent Reference: Hospital UPN; Centre Reference (CIC)

I confirm that I have explained the treatment procedure and the process regarding collection and storage of data to this patient who appears to have fully understood them.

Name of person taking consent:

Job Title:

Date: Signed:

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Glossary

Anonymization - personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. Regulation (EU) 2016/679 Of the European Parliament and Of the Council. Recital 26. 27 April 2016

Pseudonymisation -the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. Regulation (EU) 2016/679 Of the European Parliament and Of the Council. Article 4. 27 April 2016