

Patient Informed consent for data collection in MATHEC-SFGM-TC data base

The French speaking Society for Bone Marrow Transplant and Cellular Therapy (SFGM-TC, www.sfgm-tc), in direct collaboration with the European Society for Blood and Marrow Transplantation -EBMT, (www.ebmt.org) is a long standing established and not for profit academic society, well recognized in the field of hematopoietic stem cell transplantation and cell therapy. Since its creation in 1970s, the SFGM-TC members use the EBMT international database, known as the EBMT registry, that has been established to collect clinical data on patients treated with haematopoietic stem cell transplant or other type of cell therapy, their diagnosis, their treatments, complications and results of these treatments.

Members of the Center of Reference MATHEC network (www.mathec.com, Autoimmune Diseases and Cellular Therapy), established within the national Health group for Auto-Immune and Auto-Inflammatory Rare Diseases (FAI2R) and under the aegis of the SFGM-TC, are working in collaboration with the various experts of the accredited centers for allogeneic bone marrow transplantation and cell therapy to improve the management of patients with non-malignant autoimmune and autoinflammatory (AID) diseases treated with cell therapy. In accordance with the SFGM-TC Good Clinical Practices Guidelines and the 3rd National Plan for Rare Diseases (PNMR3), and according to the National Health Department Direction for health care organization (DGOS), the members of MATHEC network contribute to patient's clinical and biological data collection in the MATHEC-SFGM-TC database, as recommended following national (SFGM-TC) and international (EBMT) recommendations on data collection for patient follow-up. The aim of MATHEC-SFGM-TC database is to collect data, which are key to patient follow-up and will be used to improve patient care and develop research in the field of transplantation and cell therapy.

Data collected are stored in a secure electronic database in accordance with the **General Data Protection Regulation (GDPR), issued by the European Union. Only European countries following this regulation, whether or not they are members of the European Union, can host data.** The database is protected by measures ensuring security, in compliance with the NEN7510 / ISO27001 certification, and a rigorous access control policy with a declaration to the CNIL on July 17, 2017.

Personal data collected is limited to your initials, date of birth and gender necessary to ensure that the collected data is correctly stored in the same folder. Personal data is not used and cannot be used for the identification of individual. This process is known as "pseudonymization", which is defined in the GDPR. Each patient is registered in this database under a unique and non-informative number, which will be the one used for research purposes. No one outside the hospital where you are being treated will be able to identify you as an individual from the stored data. Your data will increase the quality of the database and thereby contribute to improve care and patient outcomes.

To achieve the objectives described above, the members of the CRMR MATHEC and the SFGM-TC networks work with many international partners, including researchers from scientific or clinical institutions, the European Medicines Agency (EMA), the pharmaceutical industry and other healthcare institutions and providers.

Through the MATHEC St-Louis Center of references for rare Autoimmune Diseases (CRMR) and the SFGM-TC, the hospital where you are being treated also share the data from this database with the following institutions:

- The SFGM-TC, an academic not for profit association bringing together French-speaking people who work in transplant centers and / or your transplant service carries out studies on the data of this register,
- EBMT, a recognized European savant society in the field of hematopoietic stem cell transplantation.
- The Biomedecine agency (ABM), a French national health agency under the Ministry of Health.

With such collaborations, your pseudonymized data could be sent outside the countries covered by the GDPR of the European Union. Patient data sent outside of this area as part of MATHEC-SFGMT-TC research projects will be identified by the non-informative database number and personal data such as date of birth, initials or the unique patient number used by the hospital will not be exported.

GDPR (<https://www.eugdpr.org>) of the European Union's regulates the collection and storage of personal data. The purpose of this regulation is to guarantee your privacy as a patient contributing data to scientific research. To comply with these regulations, you must give your informed consent for the collection and storage of your data before it can be shared with any other institution. With your authorization, the MATHEC St-Louis CRMR and the other institutions to which you have given your consent, will keep your data indefinitely so that it can be compared to the data of other patients. If you are giving your consent on behalf of a child for whom you are the legal guardian, please explain to the child, to the extent of their understanding, that their data will be recorded in a database as well as the intended use of its data.

If you do not give your consent, your data will not be collected in the MATHEC-SFGM-TC database and not used for research purposes.

If you give your consent, the data held by the MATHEC St-Louis CRMR and the associated institutions will remain under your control.

In accordance with the law, you will be able to access, directly or through your doctor, to all of your medical data, and use your right of rectification concerning your data.

You also have the right to request that your personal data be completely erased from the MATHEC-SFGM-TC database and from the databases to which your data has been exported. Children and young people also have the right to withdraw their consent when they reach the legal age of majority, by contacting doctor.

If you agree to have your data collected in the MATHEC-SFGM-TC database, please complete the form below to give your consent to the collection of data concerning your disease and your transplant.

Consent form for the collection of patient data in the MATHEC-SFGM-TC registry

I the undersigned

Last name.....

First name

(Parent, guardian, of

Certify having been hospitalized for treatment by autologous bone marrow transplant at the hospital (Department of hematology and cell therapy) and wished to be followed from now on by my usual referring physicians, in conjunction with the MATHEC reference center if necessary.

Have received information concerning the collection and registration of data regarding my hematopoietic stem cell transplant or my cell therapy and follow-up in the MATHEC-SFGM-TC database.

Accept that the data concerning my transplant or my cell therapy or that of my child be transmitted and used confidentially by the MATHEC network under the conditions provided for by law for the purposes of quality control and research.

I also agree that SFGM-TC, EBMT and ABM have access to this data for studies for research purposes.

Date

Last, first name of the physician
who gave the information

.....

Last, first name of the patient

.....

Signature :
(Stamp of the hospital)

Signature :