

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

1. The SFGM-TC and MATHEC

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 registry, as recommended following national (SFGM-TC) and international (EBMT) recommendations on data collection for patient follow-up.

2. The MATHEC-SFGM-TC registry

The aim of the MATHEC-SFGM-TC registry is to collect the key data from your medical report, which are essential for your medical follow-up and that will be used to improve all patients care and develop research in the field of hematopoietic transplantation and cell therapy. Data reporting contributes to improve the quality of care and is required by medical center to obtain FACT-JACIE accreditation. According to Good Clinical Practices and the French and EBMT guidelines, data managers from the St-Louis Center of Reference for Rare Autoimmune Diseases (CRMR MATHEC St-Louis) and from the SFGM-TC work in collaboration to ensure that data collection and data entry in the registry have content validity. Analysis from the data registry shows the annual activity performed by each center and overall, allowing annual report of the number of hematopoietic stem cell transplantation and cellular therapies for autoimmune diseases to the health authorities. The list of retrospective or prospective studies based on the use of MATHEC-SFGM-TC registry data is available on the MATHEC and the SFGM-TC web sites (www.mathec.com; www.sfgm-tc.com).

3. Data collection and storage in the MATHEC-SFGM-TC registry

3.1 Pseudonymized personal, medical and biological data collection

In addition to the collection of clinical and biologic data, which are key for patient care and follow-up, personal data collection is performed and restricted to your initials, date of birth and gender, which are 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 any individual. This process is known as "pseudonymization", which is defined in the General Data Protection Regulation (GDPR). Each patient is registered in this registry under a unique and non-informative number, which will be 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.

3.2 Data storage

Data collected are stored in a secure electronic database in accordance with the 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 previously declared by the AP-HP for MATHEC to the "Commission Nationale de l'Informatique" (CNIL) on July 17, 2017.

3.3 Data access

Direct access to the MATHEC-SFGM-TC registry is limited to MATHEC or to SFGM-TC research staff and authorized staff in your hospital. The partners defined below may have access to your personal data via the CRMR St-Louis MATHEC or the SFGM-TC.

Access to the data in your medical file is necessary to update the information contained in the MATHEC-SFGM-TC registry and to check the quality of the data. This access is performed in accordance with the current regulations and is strictly limited to a few people, defined as below:

- To the staff of the hospital where you were treated, where access to your medical data is essential for your treatment, provided that you do not object to this access;
- To an instructor or an auditor authorized by the CRMR St-Louis MATHEC or the SFGM-TC;
- To a person mandated by a competent authority to verify the quality of the data.

All parties have a duty of confidentiality to you as a research participant.

3.4 Access to the pseudonymized personal data

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 CRMR and the SFGM-TC, the hospital where you are being treated may share the pseudonymized personal data from this registry 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,
- The EBMT, a recognized European savant society in the field of hematopoietic stem cell transplantation and cellular therapy
- The Biomedecine Agency (ABM), a French national health agency under the Ministry of Health.

In the event that the country receiving the data does not have a data protection law of an equivalent level approved by the European authorities, the CRMR ST-Louis MATHEC, or the SFGM-TC, undertakes to implement binding legal measures with this partner in accordance with the European regulations, and to guarantee a level of protection of your personal data and of your rights in accordance with the European Union bylaws.

3.5 Legal basis for data processing

The General Data Protection Regulation (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 for as long as it is necessary for scientific research and improvement of patient care in the field of hematopoietic stem cell transplantation, cell therapy and autoimmune or auto inflammatory diseases.

3.6 Your rights

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 data stored in the data registry, and use your right of rectification concerning your data. 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.

You have the right to withdraw your consent at any time, without affecting the type nor quality of the care provided and the treatment administered. The processing that will have been done of your data before the withdrawal of your consent will remain legitimate. You also have the right to request that your personal data are completely erased from the MATHEC-SFGM-TC registry and from the databases to which your data may have been exported. Finally, you can request the limitation of your data as well as their portability. 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 wish to file a complaint about the processing of your data in this register, you can file a complaint with the national data protection authority: the Commission Nationale de l'Informatique et des Libertés (CNIL) in France (www.cnil.fr).

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

3.7 Contact for further information or to exercise your rights

In your hospital : Name : Function/Title : Adress : Telephone number :	
MATHEC-SFGM-TC Data base manager CRM MATHEC, Hôpital Saint-Louis Pr Dominique Farge 1 avenue Claude Vellefaux 75010 Paris Email : dominique.farge-bancel@aphp.fr Tél : 01 42 38 50 93	Data Protection Officer APHP : protection.donnees.dsi@aphp.fr

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 my personal data (cf chapter 3.1), those concerning my hematopoietic stem cell transplantation or my cellular therapy, as well as those concerning my clinical and biological follow-up, to be recorded in the MATHEC-SFGM-TC registry under the conditions provided for by law for the purposes of quality control and research.

I agree that my pseudonymized data will be shared with SFGM-TC, EBMT and ABM for research purposes.

I agree that my pseudonymized data being sent and used outside the European Economic Area for studies, provided that the same level of personal data protection is respected.

Date

Last, first name of the physician
who gave the information

.....

Last, first name of the patient

.....

Signature :
(Stamp of the hospital)

Signature :