Personal data processing for the

European Rare Blood Disorders Platform

(ENROL)

INFORMATION SHEET AND CONSENT FORM

You are invited to take part in ENROL, the European Rare Blood Disorders Platform, a European patients' registry for Rare Haematological Diseases. Participation is voluntary and requires your written consent. Please read this information carefully and ask your medical doctor for an explanation if you have any questions, including:

1. What is ENROL and what are its objectives? Definition, needs and aims
2. Who is in charge of ENROL and how is it funded? Consortium members, Data Protection Officers, funding
3. Which kind of information will be included in ENROL and how will it be processed? Data gathered
4. Will my data be re-used by other third parties? Permission to re-use your data by other third parties: Rules and process that regulate the sharing of data
5. Will I be re-contacted by my medical doctor to participate in research projects and/or clinical studies? Procedure related to the permission to be re-contacted about participating in future research projects
6. How would I benefit from my participation in ENROL? The added value of your contribution
7. Are there any potential risks of participating in ENROL?
8. How can I find out about who is using ENROL and what has been done with my personal data? Public information regarding projects with access given to ENROL data
9. For how long will my data be stored in ENROL? What if I decide that I don't want my data to be used anymore? Withdrawal of your consent

1. What is ENROL and what are its objectives?

Health professionals and researchers need to pool data from patients to understand the course of a disease and investigate new diagnostic procedures and treatments in order to improve the healthcare delivered to patients. However, when it comes to rare diseases, due to the small number of patients, it is often difficult to gather enough data at the country level to check efficiency (how well a treatment works) and safety of a new healthcare treatment or procedure. For this reason, the collection of patient data across Europe will improve the research which can be done and the healthcare services which can be provided to patients with a rare disease including rare haematological diseases.

In order to enable this European collaboration, on the 1st March 2017, the European Commission officially established European Reference Networks which are networks of experts in 24 medical areas covering rare diseases, https://ec.europa.eu/health/ern_en. The main goal of European Reference Networks is to promote equal access to the best healthcare for European citizens living with a rare disease. In addition, in 2019, the European Commission established the European Union Rare Disease Platform (EU-RD-Platform), https://eu-rd-platform.jrc.ec.europa.eu/ , as an umbrella platform for pooling data from patients affected by any rare disease across Europe.

EuroBloodNet, www.eurobloodnet.eu, is the name of the European Reference Network for rare haematological diseases, which are rare diseases that affect the blood.

The European Blood Disorders Platform, called ENROL, http://eurobloodnet.eu/enrol , is the EuroBloodNet umbrella platform for European patient registries on rare haematological diseases, aiming to pool data from patients affected by these diseases in Europe. This pooling of data will allow research and development of new treatments. In turn, this will increase knowledge of rare haematological diseases and promote guidelines and other best practices across EU.

2. Who is in charge of ENROL and how is it funded?

ENROL is led and managed by a consortium which includes the following members:

- Dr. María del Mar Mañú Pereira (Hospital Universitari Vall d'Hebrón – Vall d'Hebrón Institut de Recerca, Barcelona, Spain – Coordinator of the platform),
- Prof. Béatrice Gulbis (Hôpital ERASME, Brussels, Belgium),
- Dr. Marina Kleanthous (Cyprus Institute of Neurology and Genetics, Nicosia, Cyprus)
- Prof. Pierre Fenaux (Assistance Publique - Hôpitaux de Paris, Paris, France)

The consortium members are joint controllers of the data registered in ENROL according to article 26 of the General Data Protection Regulation (EU) 2016/679 of 27 April 2016. Each member of the Consortium has a Data Protection Officer.

The Data Protection Officer of Hospital Universitari Vall d'Hebrón – Vall d'Hebrón Institut de Recerca is based in Hospital Universitari Vall d'Hebrón – Vall d'Hebrón Institut de Recerca and can be contacted through dpd@ticsalutsocial.cat.

The Data Protection Officer of Hôpital ERASME is based in [……] and can be contacted through [……]

The Data Protection Officer of Cyprus Institute of Neurology and Genetics is based in [……..] and can be contacted through [……].

The Data Protection Officer of Assistance Publique - Hôpitaux de Paris is based in [……..] and can be contacted through [……].

ENROL is co-funded by the Health Programme of the European Union (under the call for proposals HP-PJ-2019 on Rare disease registries for European Reference Networks GA number 947670).

3. Which kind of information will be included in ENROL and how will it be processed?

ENROL is built in compliance with the European Union's General Data Protection Regulation (EU) 2016/679, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

Personal data allowing your direct identification and contact, e.g. your name and surname, national identity number or home address will not be collected by ENROL. Instead, your medical

information will be collected by ENROL along with a pseudonym generated by your medical doctor. This pseudonym consists of a set of combination of letters and/or numbers that is generated by your medical doctor through a pseudonymisation tool in line with the General Data Protection Regulation. In other words, the data that directly allows your identification and contact will never be transferred to ENROL.

Your medical information which will be included in ENROL is the information gathered in your routine medical care, i.e. date of birth, gender, diagnosis including genetics, blood results, symptoms and treatments received. This information corresponds to the 'Common Data Elements' defined by the EU-RD-Platform for rare disease registries, as well as a set of 'specific Elements' related to rare haematological diseases agreed upon by the Steering Committee of ENROL.

This will mean that at the European level, ENROL will allow mapping of the following important information concerning patients affected by rare haematological diseases: demographics survival rate, methods for diagnosis, the main clinical features and treatments.

4. Will my data be re-used by other third parties? Permission to re-use your data by other third parties.

Research is often carried out in collaboration with other international researchers from public or private sectors. By sharing research data, more questions can be answered.

Your pseudonymised data held by ENROL could be shared with third parties (i.e. researchers, patient organisations, health authorities, pharmaceutical and other commercial companies). These research projects will have objectives which are directly connected to ENROL's aims. These research projects may include those seeking to increase knowledge of the disease and the development of new treatments within academic/hospital/pharmaceutical research projects. We ask specifically for your permission to re-use your pseudonymised data for these kind of research projects.

As previously indicated, ENROL gathers pseudonymised data, which means that information allowing you to be directly identified has not been transferred to the ENROL platform, therefore, the risk of re-identification of patient data is almost impossible (see also 7. Are there any potential risks from participating in ENROL?).

ENROL will only share your pseudonymised data with third parties if the following appropriate safeguards to protect your data are in place during and after the study undertaken by the third party:

Third parties interested in accessing data held by ENROL will be required to submit an application form that details the scientific purposes of the project for which the data is needed. Requests are reviewed by a Data Access Committee comprised of both health professionals and patient representatives that ensure that the request aligns with the purpose of ENROL and its Policy. The research applicant's professional background is also reviewed to ensure they are suitably qualified and have a track record of integrity as a researcher in this area. Researchers may come from both public and private institutions in any country, including non-EU countries.

Where required by the local applicable law the research will need the approval of an Ethics Committee.

All third parties will be required to sign legal agreements requiring them to respect EU legislation and commit to:

(i) using the data only for the purpose intended and authorised;
(ii) not attempting re-identification of the data, including the merging of ENROL's data with other sources of data; and therefore,
(iii) not contacting patients directly.

In addition, in cases where data is transferred to non-EU countries, the same level of protection and commitments provided by the EU General Data Protection Regulation with regard to data protection is required.

You are able to find more detailed information on the legal framework and the process required to request data from ENROL using the following link http://www.eurobloodnet.com/enrol/legal-frame/

5. Will I be re-contacted by my medical doctor to participate in research projects and/or clinical studies?

Some of the third parties requesting data from ENROL may contact your medical doctor to request your participation in a research project and/or clinical trial for new treatment options. Since third parties will not have your personal data allowing your identification, your medical doctor will need to re-identify you from the pseudonym to ask you whether you would like to take part in the third party's study. In light of this, we are also requesting your permission to be re-contacted through your medical doctor to be offered these kinds of opportunities.

To be clear, if your medical doctor becomes aware of a research project and/or clinical trial by different means than ENROL and considers you to be eligible your medical doctor will always contact you to provide information. Your decision whether to participate or not in the proposed research project and/or clinical trial has no impact on your right to be treated according to the best standard of care available for your clinical condition.

6. How would I benefit from my participation in ENROL?

You will not directly benefit from participating in ENROL. However, ENROL aims to link people living with rare haematological diseases with researchers who are developing novel ways to prevent the disease as well as to treat it, and therefore improving the understanding of the disease you have, which could potentially benefit you in the future.

7. Are there any potential risks of participating in ENROL?

Even though ENROL has processes in place to ensure your personal information is protected, there is a small risk that data in the ENROL registry could be matched with identifiable information you have already authorised to be publicly available in databases such as ancestry websites or public rare diseases registries. To minimise this risk, those who request access to the ENROL data will agree in writing not to try to identify you by any means. However, we

recommend that you are cautious about placing your personal information on publicly available websites or registries.

8. How can I find out about who is using ENROL and what has been done with my personal data?

Information about projects which have been given access to ENROL data is publicly available on the ENROL website. In addition, you can request information on the specific projects that have accessed your data from your medical doctor.

9. How long will my data be stored in ENROL? What if I decide that I don't want my data to be used anymore?

Your data will be stored in ENROL until such time as the objectives of ENROL have been met, which may be several decades from now. However, the need to keep your data in ENROL will be reviewed every 15 years.

In addition, by contacting your medical doctor or the Data Protection Officer of your medical centres through …….[to complete]……, you can request access, rectification (correction) or deletion of your data in ENROL.

You can also withdraw your consent to participate in the ENROL registry at any time and without giving a reason. If you withdraw your consent, your data will stop being processed from the moment of receiving the withdrawal. However, in order to guarantee the validity of the research, the data which has already been collected and processed before the time of withdrawal cannot be deleted.

In summary, ENROL stores data from patients affected by a rare haematological disease at the European level with the aim of gathering sufficient scientific evidence for research analysis and interpretation leading to an increase of knowledge about the disease which allows the development of new therapies.

The data is stored with the proper security measures for such aims, including pseudonymisation, in line with the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 and the European Union recommendations for patients' registries on rare diseases.

Pseudonymised data can be shared with third parties who legally commit to its lawful use, including not attempting to re-identify patients. Patients are encouraged to review all the information provided regarding the use of data.

CONSENT

I……

with ID card number……

As • Patient

• Legal representative* of ……

** Patients not able to consent for themselves (due to age or mental impairment) must be involved and understand the information contained in this document to the extent permitted by their comprehension grade and maturity.*
The age to which the capacity of consent for processing of data is recognized, varies according to national legislation. It is recommended that once a minor reaches the legal age of consent in their country, that they sign this information sheet and consent.
The need to ask for consent of all the persons with parental responsibility for the patient will depend on the relevant national legislation. People with parental responsibility for the patient, may sign this consent in a single document or in different ones.

born on (dd/mm/yyyy) ……

state that:

1. I have read this information sheet that has been provided in relation to the processing of my personal information by the ENROL platform.

2. I have had the opportunity to have all my questions answered.

3. I have resolved all my doubts with my medical doctor.

4. I understand that my participation is voluntary.

5. I understand that I can withdraw my consent at any time and without providing a reason, and this will not affect my future medical care.

In addition,

I consent for my pseudonymised data in ENROL to be re-used by third parties in order to contribute to projects whose objectives are directly connected to improve healthcare provision for rare haematological diseases, as described in this information sheet.

☐ YES ☐ NO

I consent for my pseudonymized data in ENROL to be transferred to third parties in non-EU countries (if they legally commit to the same level of protection provided by the EU General Data Protection Regulation) in order to contribute to projects whose objectives are directly connected to improve healthcare provision for rare haematological diseases, as described in this information sheet.

☐ YES ☐ NO

I consent to being re-contacted by my medical doctor in order to be informed about opportunities received through ENROL to participate in a research project and/or clinical trial related to my condition, as described in this information sheet.

☐ YES ☐ NO

Date:

Patient's name:

Patient's signature:

Date:

Medical doctor's name:

Medical doctor's signature:

If different than medical doctor:

Name of person explaining the information sheet:

Signature of person explaining the information sheet:

The study participant will receive the full information sheet, together with a copy of the signed consent form.