

Information on data protection in the study Finnish Hematology Registry

The European Union's data protection legislation has been updated with the new General Data Protection Regulation (GDPR), which entered into force in May 2018. This regulation requires the secure processing of personal data and gives individuals important rights concerning their own data. One of the most significant changes concerns information that should be provided to individuals in situations in which their personal data is collected.

The FHR study is based on the written consent of the subject. The signed consent includes a paragraph on the confidentiality of data and data protection. It explains how information on the subjects is collected and used and specifies the rights of the subjects.

This information leaflet contains detailed information on the provisions of the GDPR, including

- Data can be processed using automation technology such as computers
- The data is retained for as long as required by law
- Information on the person to be contacted in case of questions or if the subject wishes to exercise their rights in accordance with the privacy statement
- Information on the right to file a complaint with the data protection authority, if necessary

The other principles of the General Data Protection Regulation are already included in the signed "Information leaflet on the study and consent to the study" document, which is a prerequisite for participation in the study.

Background and objective of the FHR study

The aim of the FHR study is to collect information on blood diseases in Finland. There are numerous types of blood diseases, and the vast majority of them are rare diseases, i.e. they occur in <1/2000 people in the population. The emergence of many of these diseases, i.e. the number of new patients per year, is approximately 1–5/100,000 persons. In such a situation, it is only by means of national data collection that information can be obtained on an adequate number of patients to make proper estimates. The establishment of studies separately for each disease is challenging, and, in practice, the required permits and technical applications enabling the activities are the same for all of them. By pooling resources, a person who has been diagnosed with a blood disease may be asked to participate in the FHR study. The disease may be associated with excessive coagulation or excess bleeding tendency, or it may involve underproduction or overproduction of primary blood cells. In practice, the majority of persons with this diagnosis are examined and treated in units specialized in hematology and coagulation disorders. The data that is relevant for the disease in question can be collected from subjects who have given consent to it into a browser-based database, which contains data collection forms modified for each disease. The accumulated data can then be analyzed with respect to their emergence, diagnostics, the treatments used, and treatment outcomes. The goal is to obtain a more accurate picture of the treatment of blood diseases at the national level. The research is conducted by the treating physicians and the research nurses in charge of recording the data, who are adequately qualified for blood diseases. The research centers are the units that treat Finnish hematology patients.

What personal data is collected?

The basis of the study is data collection. Data collection for the study register involves the collection of personal data such as name, gender, personal identity code, and health information concerning other diseases and the diagnosed blood disease in particular. Hence, the data collected for different diseases will vary, and the data will focus on the results of blood tests, tissue samples and imaging that is relevant for each disease. Registration of the personal identity code ensures that the data collection is performed correctly for each subject. The data source is the patient record system of the subject's treatment unit and the data accumulated in it. This study does not involve any additional sampling or other procedures. If necessary and to the extent permitted by law, information about your health may be collected with your consent also from other health care units that contain your patient data and registries containing your health data.

The study register operates in such a way that your personal data is displayed in the treatment unit in the same way as in the patient record system, but only your age, birth date, and gender are visible for users who access the register from elsewhere, and you cannot be identified via the register.

Version 1, 17 August 2018

How is personal data used?

The collected data, including personal data, is used to verify the results of the study. In order to obtain information on each blood disease nationwide, the data will be studied together with the data of the other subjects participating in the study.

After the storing phase, data processing is mainly automated. This means that the data will be processed using computer programs.

By providing your consent, you agree that your data, in practice your patient records, may be used in the manner described above.

The accumulated data must be analyzed in order for it to provide information that will benefit the treatment of blood diseases and the quality of treatment nationwide. The study protocol does not unambiguously specify this analysis. In addition to general indicators such as incidence, prevalence, and life expectancy, the use of different treatments for diseases may be studied.

The research teams may request data from the register for analysis. Data may also be disclosed from the register to the pharmaceutical industry. The data disclosed from the register is always pseudonymized, that is, a code number is used of the subjects and an individual person cannot be identified on the basis of the data.

Where is the research data stored?

Based on the agreement with Granitics Oy, which implemented the research database, the data collected in the study is stored on a server that fulfils the security requirements for processing sensitive data and corresponds to the electronic systems used by insurance companies and banks. The study register can only be accessed by authorized persons, and access is only possible from pre-defined IP addresses. The aim is that data will be accumulated at least until 2030 and retained after the completion of the study for as long as required by law.

Results obtained on the basis of the data collected in the register may also be published at medical meetings or in journals. If the results are published, the subjects cannot be identified from the publication.

Who can see the research data?

Data is saved in the study register by the treating physicians and research nurses on subjects in their own hospitals. In addition, research nurses may be used who store data from more than one treatment unit. The collected data is in the patient record system and is stored from there into the study register. Data stored in the study register is protected in accordance with data protection requirements.

- Study physicians and the personnel of the research center. The treating physicians in each treatment unit act as study physicians. The data is the same as the data that these physicians would see via the patient record system.
- It is also possible to view data stored in the register from other research units. In this case, the data is displayed without any identifying information about the participant; however, age, date of birth, and gender are shown.
- Data may be disclosed from the register for further analysis. In this case, any identifying information about the participant, such as name and personal identity code, will be removed. Further analysis is conducted by individual academic researchers and research firms assisting pharmaceutical companies. They must accordingly comply with the requirements of the GDPR referred to in this information leaflet.

What rights do I have to my research data?

You have the right to inspect your personal data entered in the patient record system. This data is used as a source of information in this study, and any changes made to the data in the patient record that is relevant to the study is also exported to the data in the study register. The majority of the data collected consists of the results of various examinations, so there should be no particular need for you to inspect it in the study register. If you withdraw your consent, the collection of data will cease. If the data collected prior to the withdrawal has been used as part of further analyses, it cannot be completely removed, but the identifying details will be deleted.

If you have questions about the collection or use of the data or wish to withdraw your consent, you may contact the person in charge of the study.

Up-to-date contact information can be found at

<https://www.hematology.fi/fi/shy/shr/yhteystiedot>

You also have the right to lodge a complaint with the Data Protection Ombudsman if you consider it necessary. The contact information can be found in the FHR privacy statement.