Description of the processing of personal data in the study register 4 September 2018	Regulation (EU) 2016/679 of the European Parliament and of the Council (EU General Data Protection Regulation, GDPR)
1 Register controller	**Name:** Suomen hematologiyhdistys ry (Finnish Hematology Association) (SHY) Hematologföreningen i Finland r.f. Business ID 1482459-6 **Contact information** Chair Taru Kuittinen, Head of Department Kuopio University Hospital, hematology Kelkkailijantie 7, PL 100, 70029 KYS Phone: 044 717 6962 email: taru.kuittinen@kuh.fi
2 Person responsible for the register	Person responsible for the register: Perttu Koskenvesa, physician responsible for the register Helsinki University Hospital, Comprehensive Cancer Center, Hematology Haartmaninkatu 4, P.O. Box 372, FI-00029 HUS tel. 050 4286281 perttu.koskenvesa@helsinki.fi
3 Contact information in matters relating to the register	Perttu Koskenvesa Research Nurse Anne Gesterberg tel. 040 7706359 anne.gesterberg@hus.fi
4 Register name	**Finnish Hematology Registry, FHR**
5 Purpose for processing personal data	The register will be established for the purpose of scientific research. To ensure the individual identification of patient records, personal identity codes must also be stored. The formation of the register is based on a study: **The Finnish Hematology Registry: Population-based follow-up study on the emergence, incidence, diagnostics, treatments and treatment outcomes of blood disorders and inherited bleeding disorders in Finland** Lead researcher responsible for the study: Kimmo Porkka, Professor, Head Physician Helsinki University Hospital, Comprehensive Cancer Center, Hematology Haartmaninkatu 4, P.O. Box 372, FI-00029 HUS The starting point of this study is that the up-to-date data on the emergence, incidence, diagnostic methods, treatments, and prognosis of blood disorders covering the whole of Finland is incomplete, which makes it difficult to develop and assess the quality of treatments. Only through a comprehensive, population-based register can the treatment of blood disorders be systematically developed and the high quality of treatment

	ensured in all treatment units. The data to be collected can also be used to estimate the breakdown of treatment costs and assess the impact of the adoption of new treatments to the cost structure of the treatment units and the whole health care system. The objective of the Finnish Hematology Registry (FHR) study is to accumulate and analyze data on the emergence, incidence, diagnostic methods, treatments, follow-up, and prognosis of the studied diseases in Finland. In the future, the data gathered through the FHR study will be a key tool in planning the treatment of blood disorders and providing consistent treatment nationwide.
6 Grounds for processing personal data	Written consent given by the subject. Consent is requested from persons diagnosed with a blood disease or coagulation disorder. (ICD-10 diagnosis codes C81-96, D45-64, D66-68, and D69-76). The processing of personal data described above is based on provisions including: • EU General Data Protection Regulation (2016/679) • Article 6 (1) (a) processing of personal data based on consent • Article 6 (1) (e) processing is necessary for the performance of a task carried out in the public interest • Article 9 (2) (a) processing of health-related personal data based on consent • Medical Research Act 1999/488 • Archives Act 23.9.1994/831 • Act on Health Care Professionals 28.6.1994/559 • Act on the Status and Rights of Patients 17.8.1992/785
7 Data content of the register	Identifying details: Personal identity code, date of birth, hospital responsible for treatment, hospital district. Data concerning the disease being studied: The information required to make a diagnosis, treatments, treatment outcomes, follow-up data, functional capacity, laboratory results, radiology and pathology results. In practice, the examination results considered relevant for each disease are stored. The variable lists per disease may be viewed on request. The FHR study does not involve any data collection in addition to that conducted in normal treatment practice. Data obtained through other studies, such as data on quality of life and examination samples, such as blood and bone marrow samples, may be stored in the register. In this case, the taking of samples is based on other studies with research permits, and the data collected through the FHR study will serve as clinical data to be combined with the samples. Consent register: • consent of the subject to the registration of data, date of consent • a code number is generated for the subject when the consent is saved • storage location of paper consent forms Data register:

	• data collected about the subjects: diagnoses, treatment events and outcomes; medications used for the treatment of blood diseases; other diseases and the related medical treatments; laboratory, imaging and other examination results; well-being/health/lifestyle data to the extent available in the patient record • participation in clinical drug trials or other data collection or sample collection studies conducted in the categories of diseases • information on consent given for the collection of biobank samples for FHRB. The subject has provided separate written consent for the collection of FHRB samples and data collection. Register of authorized users: • data on authorized persons: name, email address, mobile phone number, user ID, type of user, categories of diseases visible, hospital of employment, participation in studies related to registered diseases, date of granting access rights and issuer, and time of most recent update to access rights • the authorized user must sign a separate commitment to comply with the data protection and confidentiality rules. The written commitment forms are stored by the person responsible for the register. • A log entry is saved in the register of logins to the register and the storage operations performed there by the user. These can be used to monitor the proper use of the register. The data is stored using electronic data collection forms (eCRF), which have been modified for each diagnosis. No permanent manual material will remain of the collected data. If the data is recorded centrally by research nurses based on printouts of patient report texts and results, the printouts are destroyed in a secure manner. Consent is collected from the subjects on paper forms. The consent forms are store centrally in the treatment unit that received the consent. The consent forms are stored in locked premises.
8 Regular data sources	Data is obtained as follows: • Through the research team's activities in the context of the study • Patient documentation (patient record and the related documents, such as laboratory, x-ray and other examination results) in the treatment units. • Instead of manual storage, automatic data transfer may be used for laboratory results, for example, if the technical capabilities are available in the research units • Storing personal identity codes is necessary to ensure the identification of the subjects during storage • The idea of the FHR study is the collection of data, and the analyses made on the basis of the collected data will be more accurate along with the growing accumulation of data. All the analyses seek to answer questions that improve the quality of treatment in accordance with the study title.
9 Categories of recipients of personal data	Recipients of personal data associated with the study: • Treating physicians and nurses act as presenters of the study and recipients of consents

	• The treating physicians, nurses, and ward secretaries in the treatment units and, separately, research nurses are responsible for storing data • Granitics Oy acts as the technical administrator of the Finnish Hematology Registry and as a processor of personal data as defined by the new EU General Data Protection Regulation. The operation of Granitics Oy will comply with the GDPR when it enters into force on 25 May 2018. Granitics Oy also requires GDPR compliance from all parties involved in the processing of personal data.
10 Regular disclosure of data	The register is available in a browser-based environment for authorized users. The register personnel (responsible physician, research nurses, coordinator appointed by the Finnish Hematology Association) have more extensive rights to process the data. The treating physicians of each responsible treatment unit can view all the data on their patients, including identifying details. Data on patients diagnosed in other units will be displayed without identifying details. Example of data that can be used: Male, born 1954, CLL. Data will be reported to the European Medicines Agency (EMEA) according to its requirements as needed. This would involve reports drawn up on the basis of data collected at a general level without the disclosure of data on individual subjects. Data will be disclosed for use by registers under the European LeukaemiaNet (a European cooperation organization for the research and treatment of blood diseases) in pseudonymized form with a study code number in the form required by the registers to the extent possible. Data can be similarly transferred to the register of the corresponding organization for hemorrhagic diseases, the European Association of Haemophilia and Allied Disorders. Nordic disease-specific research teams also have register projects to which data can be disclosed in coded form. No identifying information on individuals will be disclosed to international registers. Individual researchers or research teams may request permission from the Board of the Finnish Hematology Association to access and analyze data collected through the study. The data is disclosed for approved projects in pseudonymized form without any possibility of identifying an individual. Individual subjects are not identifiable in reports or publications based on the analyses. The disclosure of data in accordance with the principles outlined above is also possible outside the EU or the European Economic Area, if the level of data security in that country is at the level of the EU.
11 Retention period for the study register	The study is planned to continue by collecting data until the end of 2030. The permanent retention of documents is provided for in the Archives Act (831/1994). Permission will be requested from the National Archives of Finland for the retention of the study register, as the collected data will provide valuable reference material for future studies and continuing projects to improve the quality of treatment.

12 Rights of the data subject	The subjects have the following rights (GDPR 2016/679): • The right to withdraw consent without giving a reason (Article 7, paragraph 3) • The right of access to their personal data (Article 15) • The right to rectify the data (Article 16) • The right to erasure of the data (Article 17) • The right to restriction of processing (Article 18) o the data subject can make a free-form request, which will always be handled on a case-by-case basis Applications and requests concerning the abovementioned rights should be sent by post to the person responsible for the register. All units in which data collection is carried out will provide information on the FHR study and the existence of the resulting register and its data content. An up-to-date privacy statement and an information leaflet for study participants describing the FHR study and the resulting register activity will be made available. The leaflet will also specify the fact that the data stored in the register is collected from the patient records of the treatment unit. In practice, there is no need to separately inspect the register data, as any changes made to the patient records based on the applicable inspection right will be saved in the study register to the extent appropriate. If the subject cancels their consent, data will be no longer be saved. If the data collected previously has been used in the analyses and reporting of data, the accumulated data cannot be completely removed due to the legal protection of the researchers who conducted and published the analyses. In this case, the name and personal identity code of the person who withdrew the consent will be removed from the register, but the code number will remain.
13 Principles of register protection	**A) Data to be processed electronically** The information contained in patient records is confidential. The users of the register are bound by confidentiality with regard to the data in the register. Access to the register requires a username and password, and login requires a session-specific code that is sent to the mobile phone number specified by the user at each login. Usage is monitored by a log that stores login details and the storing of data, i.e. new data entries and the modification of existing data. Access rights are decided by the register management group set up by the Finnish Hematology Association. Access rights may be granted to treating physicians, nurses, ward secretaries, and register personnel, such as research nurses and, temporarily, researchers. Prior to obtaining access rights, users must sign a commitment to comply with the rules. The system comprises an information system implemented in the Java programming language and running on an Apache Tomcat web server and a Microsoft SQL Server database. The system runs in a Windows Server 2012 R2 operating environment. The system interface is implemented in the HTML and JavaScript languages.

	Data communication in the study register's information system is encrypted with SSL protocol. The system uses a certificate issued by a trusted third party. Access to the system is restricted at the network level by only allowing data connections from predefined IP addresses. The list of authorized access sites includes Finnish hospitals and universities. Access restriction is implemented using a firewall equipped with IDS (intrusion Detection System). The register information system is located in a secure data center that complies with the regulations of the Finnish Communications Regulatory Authority (Regulation 54B/2008 M) regarding equipment facilities with priority rating 1 or 2. The regulation applies to public communications networks and public authority networks and the communications services they provide with regard to priority rating, hardware redundancy and detour arrangements, power supply and the resilience of power supply, and physical protection. The data contained in the system is only stored in data centers located in Finland. All data in the study register is backed up with versioning once a day. The retention period for each daily backup copy is six months. If necessary, the data may be restored to the status of the desired date for that period. The database contains an up-to-date list of persons with access rights; this is also available from the person responsible for the register. **B Manual materials** Material in paper format (in practice, consent forms) is kept in locked rooms which may only be accessed by persons who handle these matters or documents.
14 Right to lodge a complaint to a supervisory authority	Without prejudice to any other administrative or judicial remedy, every data subject shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of his or her habitual residence, place of work or place of the alleged infringement if the data subject considers that the processing of personal data relating to him or her infringes the GDPR. Information on the supervisory authority: **Office of the Data Protection Supervisor** Visiting address: Ratapihantie 9, 6th floor, FI-00520 Helsinki Postal address: P.O. Box 800, FI-00521 Helsinki Exchange: 029 56 66700 Fax: 029 56 66735 Email: tietosuoja@om.fi