Parent/legal guardian information sheet for minors

Dear Parents, dear legal guardians,

Your child has been diagnosed as suffering from sickle cell disease. The individual course of this blood disease during a patient’s life cannot be reliably predicted, but it can damage potentially every organ of the human body. The collection of information about patients suffering from this rare disease could help us to improve the quality of medical care. With this goal in mind, we have initiated a Registry for patients suffering from sickle cell disease. This Registry is promoted and coordinated by a group of Universities including Berlin, Frankfurt, Hamburg, Heidelberg and Ulm. Dr. Kunz from Heidelberg is responsible for the data collection.

You will be asked to give your informed consent for the participation of your child in the Registry “Sichelzellkrankheit” (sickle cell disease). This information sheet provides you with all you need to know about this Registry. If you have understood how the Registry works and if you agree for your child to participate, please sign the consent form.

If your child does not understand what enrolment into this Registry means and cannot make an informed decision about this, you can decide for him/her. If your child is able to understand and decide, his/her opinion will be considered.

The participation of your child in this research project is voluntary and can be withdrawn at any time without giving any explanation. There are no drawbacks for you and your child in case you decide not to participate. Please take your time to make your decision and do not hesitate to ask if you have any questions.

What is the Registry studying?
The Registry aims to analyse the following aspects of sickle cell disease:

1. **What are the most common forms of sickle cell disease in Germany?** Several genetic factors influence the clinical course of sickle cell disease, including (but not only) mutations in hemoglobin genes. The gene mutations causing sickle cell disease arose independently in different regions of the world. Nowadays we find these mutations in central Europe as a consequence of historical human migration. The Registry aims to define what genetic forms of disease characterize sickle cell patients in Germany.
2. **What complications occur in sickle cell patients?** Patients with sickle cell disease can suffer from diverse complications. Many factors influence the clinical course of the disease, for example age at initial diagnosis and the type of treatment. As the situation of patients living in central Europe differs from that of patients living in other countries, we need to collect more information about the typical complications of patients living in central Europe to better understand their disease and to define appropriate therapeutic strategies.
3. **How can the clinical course of sickle cell disease be predicted?** The clinical course of sickle cell disease varies from patient to patient. The Registry aims to define some disease characteristics which can help to predict the course of the disease for each single patient or for groups of patients.

4. **How are patients with sickle cell disease treated?** In order to treat patients with sickle cell disease uniformly, the coordinators of the Registry published national guidelines for therapy. The Registry will help us to know how many patients are treated according to these guidelines.
5. **Which consequences does sickle cell disease have on the patients’ life?** Sickle cell disease is rare and largely unknown in central Europe. Patients are frequently misunderstood, e.g. limitations at school or at work may not be attributed to sickle cell disease but wrongly misinterpreted as laziness. With the help of appropriate questionnaires the Registry will investigate how much sickle cell disease restricts patients’ everyday life.

How many patients will be included in the Registry?
We plan to include approximately 500 Patients from about 50 different centres in Germany, Austria and Switzerland.

How will each centre contribute to the Registry?
The Registry will be opened in Germany, Austria and Switzerland. The physicians of each centre are responsible for the treatment of their own patients. Each treating physician will send a blood sample of their patients in order to improve the quality of the diagnosis and define the form of the disease. You will get more information about this test separately. The physicians will also collect information about the diagnosis and clinical course of their patients and report these data via an electronic database which will be managed by the Registry coordinators. Data will be collected, stored and processed in this protected database. The system complies with professional confidentiality principles and data protection rules. Please find the name and contact information of the people responsible for the Registry at the end of this document.

How long will your child be part of the Registry?
The cost for initial data collection in the Registry is covered until the end of 2018. As sickle cell disease is a lifelong disease, we plan a long-term collection of data about the clinical course of your child. You can withdraw your consent at any time and the collection of your child’s data will be terminated immediately.

Are there any risks associated with the participation in the Registry?
The participation in the registry doesn’t imply any further risk for you or your child. Collection of blood samples is expected to be performed in every child to allow a precise diagnosis and optimal therapy. On the occasion of one of these blood collections your attending physician will collect and send to a reference laboratory an additional blood sample (approximately 2 ml). This sample will be analysed for the genetic modifiers of sickle cell disease. For this genetic analysis, you will be asked for a separate informed consent.

Will you spend any time for the participation in the Registry?
The registry will collect data that are gathered routinely in all patients with sickle cell disease. No additional appointments will be required for you or your child.

Will your child have any direct benefit from participating in the registry?

Your child will not get any immediate benefit from participating in the Registry. Your child’s disease can be better described thanks to the specific diagnostic analysis in the reference laboratory. Although your attending physician is responsible for the therapeutic decisions about your child, they can ask the Registry coordinators for their advice at any time and maybe learn from the data that have been collected. In this way your child may indirectly benefit from participation in the Registry. The results of the Registry will be helpful to treat patients with sickle cell disease better in the future. You and your child will not get any financial compensation for participation in the Registry.

Will you have to pay for the participation in the Registry?
No. The expenses for the additional analysis on the blood sample and data collections will be covered by the Registry. Your medical insurance will pay for the routine treatment independently of participation in the Registry.

What rights will my child have when taking part in the Registry?
Participation in the Registry is voluntary. You can withdraw your consent at any time without giving any explanation and without any drawbacks for your child.

Will there be an insurance that covers the risks of taking part in the Registry?
No, an additional insurance will not be provided, because patients taking part in the Registry will be treated as any other patient following the national guidelines and will not receive any special therapy or be subject to additional risks.

What is meant with the terms “confidentiality” and “data protection” in the Registry?
Confidentiality will be maintained for the duration of the Registry and beyond. Only the study coordinators will have access to data that can identify patients. Pseudonymised data can be given to researchers not being part in the study coordination upon written request. Pseudonymization means, that the name of your child and other identification data are substituted by a numerical code or a letter code. Data will not be used for commercial purposes. If results of the Registry will be published, this will be done without mentioning patients’ names or other information that may allow your child to be identified.

All the people who have access to the Registry database are subject to professional confidentiality and data protection rules. You can voluntary decide if your child’s data can be stored and analysed. Your decision will not have any consequence to the treatment of your child. You can withdraw your consent at any time. If you are interested in getting more details about the data we are collecting, please ask us. We ask you to consent that your child’s personal data (including date of birth, diagnosis, medical results, therapies and other medical data) will be processed (storage, transmission, modification, deletion). The data processing will be used to describe the clinical courses of sickle cell disease in order to devise better therapeutic strategies in the future.

If you decide to withdraw your consent in the future, the collection of data regarding your child will be immediately terminated and data that were collected already will be deleted.

Did we consider the ethical aspects emerging from the Registry?

Yes, an ethics committee approved this Registry. The study satisfies the principles of the Declaration of Helsinki (World Medical Association) that provides guidelines for such studies.

What other options are possible?
You can deny the participation in the Registry. Your child will continue to be treated in the same way, no matter whether or not you consent to his/her participation in the registry.

Who can you ask if you have any questions?
If you have any questions you can ask your child’s physician.

_____ at _____
(Name and address/ Phone nr. of the attending physician)

Addresses of the Registry coordinators:

Dr. med. Stephan Lobitz, MSc
Charité - Universitätsmedizin Berlin
Campus Virchow-Klinikum
Klinik für Pädiatrie m.S. Onkologie/Hämatologie/KMT
Augustenburger Platz 1, 13353 Berlin

Prof. Dr. med. Holger Cario
Universitätsklinikum Ulm
Klinik für Kinder- und Jugendmedizin
Pädiatrische Hämatologie und Onkologie
Eythstrasse 24, 89075 Ulm

Dr. Regine Grosse
Universitätsklinikum Hamburg-Eppendorf
Zentrum für Geburtshilfe, Kinder- und Jugendmedizin
Klinik und Poliklinik für Pädiatrische Hämatologie und Onkologie
Martinistr. 52, 20246 Hamburg

Dr. med. Andrea Jarisch
Klinikum der Johann-Wolfgang-Goethe-Universität
Zentrum für Kinder- und Jugendmedizin, Klinik III
Schwerpunkt Stammzelltransplantation
Theodor-Stern-Kai 7, 60590 Frankfurt am Main

Prof. Dr. med. Andreas Kulozik, PhD
Universitätsklinikum Heidelberg
Zentrum für Kinder- und Jugendmedizin III
Im Neuenheimer Feld 430, 69120 Heidelberg

Dr. med. Joachim Kunz
Universitätsklinikum Heidelberg
Zentrum für Kinder- und Jugendmedizin III
Im Neuenheimer Feld 430, 69120 Heidelberg

Parents/legal guardian consent form for minors

Patient

Name: _____ Date of birth: _____

I / We,

- received verbal and written (Information sheet) information from the attending physician about the **Registry "Sichelzellkrankheit" (sickle cell disease)**. In particular they informed me/us about the meaning and implications of participation in the Registry, about risks and benefits, about participant rights, rules of confidentiality and data protection and information sources regarding the Registry.
- had sufficient time to think about participation in the Registry.
- got informed that participation in the Registry is voluntary and can be withdrawn at any time without giving any explanation and without any drawbacks resulting to us/our child.
- **was/were informed and agree that my/ our child's data that are collected in the Registry will be stored and analysed in a pseudonymised form and possibly forwarded in an anonymised form. Third parties will not have access to personal data. If the Registry's results will be published, my child's name will not be mentioned.**
- agree that both the personnel of the local and national health authorities responsible for the quality controls and the personnel of the Registry coordinators responsible for the quality controls, also subjected to professional confidentiality, can have access to original data in the database. In this case identification data will not be shown.
- have read all the points above and had the possibility to ask my questions personally
- agree with the participation of my child in the Registry "Sichelzellkrankheit"

_____

Attending physician / Date / Place

_____

Patient / Date / Place

O By signing this document, the parents/ the legal guardian and the attending physician attest that the patient is too young to give his/her consent for participation in the Registry

O Custodian: both parents

_____

Mother or legal custodian: Last name, first name / Signature / Date, Place

_____

Father or legal custodian: Last name, first name / Signature / Date, Place

O Custodian: one parent

I attest that I have the sole custody of my child or that my _____ agrees with me.

_____

Legal custodian: Last name, first name / Signature / Date, Place

O Custodian: guardian / caregiver

I attest to be the _____ of this child and I give my consent.

_____

Legal custodian: Last name, first name / Signature / Date, Place

The original copy of this consent form has to be stored in the patient's medical record. The patient receives a copy.