# Patient information and informed consent for the participation in the registry study for non-HFE hemochromatosis.

Dear patient!

This consent form contains important information so that you can decide if you wish to take part in a research registry. If you have any questions that remain unanswered, please ask the study doctor or one of his/her research study personnel before signing this form.

*Background:*

You have been diagnosed with an iron overload disorder which is no caused by a genetic mutation of the HFE gene (most common cause for iron overload). Therefore your suspected diagnosis is non-HFE hemochromatosis. This disease contains a variety of iron overload disorders which can be attributed to mutations in different genes related to iron metabolism. Unlike the classical HFE hemochromatosis, non-HFE hemochromatosis is not very well investigated and better clinical data on the disease is needed.

*Aim:*

We aim to elucidate the natural course, the role of specific genetic mutations, laboratory, imaging and histological changes of the disorder to improve diagnostic tools and treatment possibilities.

*Methods:*

A patient registry collects and stores patient medical information for the use in medical research. The purpose of the ***non-HFE*** registry is to collect and store medical and other information from individuals with the same or related disease. Data which is routinely determined in the clinical practice (laboratory and imaging results, diagnosis made from tissue samples and genetic findings) will be collected (pseudo)anonymized in an international database. Apart from the tests and investigations which were performed as part of the routine clinical practice no additional test or follow-up investigation is necessary for the participation in this study.

There is minimal risk in taking part in the registry. The registry may ask you to answer questions that can be sensitive and you may feel uncomfortable answering. You do not have to share any information that you do not want to share. Another possible but unlikely risk is potential breaches in the computer system. In the event the there is a breach in the registry’s computer system, you will be notified.

Particiaption in this study is voluntary. You do not have to contribute information. If you do participate, you can withdraw from the registry at any time and for any reason. Your decision about whether or not to participate in this registry will not affect your healthcare, your medical treatment or insurance benefits.

The non-HFE registry is sponsored by the European Association fort he Study oft he Liver (EASL) and there is no cost to you to participate.

*Data protection:*

One way the registry protects your privacy is to remove your name, address and other “identifying” information from your medical information before providing it to researchers. This information is “de-identified” because it has had all personal identifiers removed. Your registry information will be labeled with a code number and stored on secured computers and servers and protected with encryption and passwords. Only authorized people who work in the registry will have access to the data.

The registry will not share your information with anyone outside the registry. Approved researchers and clinicians will be allowed to see only the de-identified information. Approved researchers and clinicians may use de-identified information to conduct research and publish the results.

## *Who do I contact with questions?*

If you have any questions about the registration process or about participation in the registry, please contact the non-HFE registry at (contact@non-hfe.com).

By signing this form, you do not give away any legal rights or benefits to which you are otherwise entitled. If you do join, you can change your mind and withdraw from the registry at any time and request to remove any of your information that has not assigned yet to any specific study. You will not be able to remove any information that already has been assigned to a specific study.

Checking the boxes below and your signature means: (a) you have been given background or supplemental material and the opportunity to ask any questions; (b) you understand the content of the informed consent; (c) you have had the time to consider fully whether you want to join the registry, and (d) you agree to participate in the registry.

1. I understand that my participation in the registry is voluntary and that I can change my mind and withdraw at any time.   
   Yes
2. I understand that all attempts will be made to protect my privacy and my family’s privacy. I understand that my personal information will be protected and saved in the registry using a code. However, there is a very small risk that my identity could be revealed.   
   Yes
3. I understand that by agreeing to participate, I will be contacted by the registry to update or correct my health information regularly.   
   Yes
4. I am willing to provide my de-identified medical information to be used for clinical trials and other medical studies related to my disease.   
   Yes  No
5. I understand that my de-identified information can be used for any approved research study including diseases that are not associated with my disease. Yes
6. I understand that I may not personally benefit from participating in the registry or from the use of my de-identified medical information in any research study.   
   Yes
7. I understand that I can withdraw from the registry at any time and remove my information. I also understand that any information given previously and already assigned to a specific study cannot be removed.   
   Yes
8. If any information is obtained through the patient’s participation in this registry that has implications for the patient’s health, would you like the repository to tell you so that you can get that information?   
   Yes  No
9. I understand the content of this form and all my questions were answered. I had enough time to decide that I want to participate in this registry. I was given a copy of this consent form and background information about the registry.   
   Yes  No

Name of patient or legal representative:

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Signature of the patient/legal representative confirming that he/she understood the content of the consent form

Date…………………………………….Signature:………………………………………………………………………..

Name of the person (not relative of the patient) who explained the content of the consent form

Date…………………………………….Signature:………………………………………………………………………..