INFORMATION FOR THE DONOR (V.23-2018)

INFORMED CONSENT FOR USING AND CONSERVATION OF BIOLOGICAL SAMPLES AND CLINICAL DATA FOR BIOMEDICAL RESEARCH AND RESEARCH PROJECTS ON IRON METABOLISM AND HEMATOLOGICAL DISEASES

This document is to **request your written permission** for the free donation of biological samples and clinical data to use in biomedical research related to an imbalance of iron levels in the body.
It is important that you carefully read this informed consent sheet, you understand its content and purpose and ask all the questions you may have.

Aim of the study: Improve our understanding in iron metabolism research

The purpose of this study is to better understand the causes of the deregulation of iron metabolism and related diseases, as well as other hereditary hematological diseases. This will allow advancing in the diagnosis of these diseases and providing better predictive and therapeutic tools.

The person responsible for the study and research is Dr. Mayka Sánchez from the Department of Basic Sciences. Faculty of Medicine and Health Sciences, International University of Catalonia (UIC). The researchers in charge of these studies do not receive any economical compensation in connection with the assignment of your biological samples or clinical data.

Biological samples and associated information: Samples and their associated information will be retained for study and follow-up
To participate in the study you must donate a **biological sample** (small blood and/or urine sample and/or oral swab and/or aspirate/bone marrow biopsy surplus from clinical diagnosis). Data and sampling collection will be performed by professionals of the Hospital.

Biological samples and associated information are guarded on the conditions and guarantees of quality and safety required by the Spanish legislation and codes of conduct approved by the Ethics Committee for Clinical Research (CEIC) of the International University of Catalonia (Sant Cugat del Vallés).

With these samples we will perform clinical, genetics and/or molecular biology studies and from them we may obtain information about your health and the one of your relatives. All the data will be protected (see section on data protection and confidentiality).
By this consent, the patient is informed and aware that researchers from the research projects referred herein may only access to his/her medical records to consult and obtain relevant information.

In addition, this consent is requested to authorize the storage of samples during the period required to complete the study, and if necessary, sending samples and clinical information to reviewers and experts from these research projects.

The collection of samples may be used by the researchers mentioned here or by third researchers by free transfer and only for a line of research related to the initial proposal and after requesting a new specific informed consent for the new project.

Discomfort and possible risks. There is no significant risk to participants
The only inconvenience may arise from the blood draw. Sampling can cause a burning sensation at the point where the needle is inserted in the skin and cause a small bruise or a minor infection that goes away in a few days. More rarely dizziness can occur at the time of blood collection.
The tissue sample is derived from the care process and clinical diagnosis to which you have voluntarily submitted. Only a fraction is retained for use in biomedical research.

Data protection and confidentiality. Samples are kept encrypted and confidential

Samples and personal data will be stored in the **collection of biological samples of human origin** of UIC (directed by Dr. Maria Carmen Sánchez Fernández) registered with number C.0000383 in the Register of samples collections dependent of the Spanish "Instituto de Salud Carlos III". All information regarding the personal data of patients or controls included in the study will be strictly confidential in accordance with the Organic Law on Data Protection (Law 15/1999) and in accordance with Regulation (EU) 2016/679 of the European Parliament and the Council of April 27, 2016 on Data Protection (RGPD) that is fully applicable in the EU as of May 25th, 2018; complying at all times with the duty of secrecy and confidentiality. The identification of biological samples will be subjected to an encoding process. An identification code is assigned to each sample, which is detached from personal data. Only authorized personnel can connect the code with the identity of samples and data.

Furthermore, even if the results of the research performed with your samples are published in scientific newsletters, in any case your identity will be given.

Sample and research results belong to UIC, and if so, to the principal investigator, in order to manage the use of the material given by you for research purposes described herein. You can exercise at any time, access rights, rectification, cancellation or opposition by written position and attaching a photocopy of ID card or passport, addressed to Dr. Mayka Sanchez, Department of Basic Sciences. Faculty of Medicine and Health Sciences, International University of Catalonia (UIC), Josep Trueta, s/n, 08195 Sant Cugat del Vallès, Barcelona, Spain.

Altruistic donation. Your transfer of biological samples is free

This donation is altruistic by law and for this reason you cannot obtain any current or future economic benefit nor have rights for potential business benefits of discoveries that can be obtained as a result of biomedical research.

Benefits. Society will benefit

The knowledge gained from the studies carried out from your samples help the medical advance and are a great benefit for society. However it is possible that your participation in this study has not direct benefit.

Voluntary participation: Your refusal will NOT affect your actual or future medical care

Your participation is completely voluntary. If you sign the informed consent, you confirm that you want to participate. You can refuse to participate or withdraw your consent at any time without giving any reason and without worsening your medical care.

Withdrawal of consent. If you decide to sign this consent, you can also cancel it

If you would like to withdraw your consent in the future, your biological samples would be destroyed and the data associated with them would be eliminated. You may also ask for the anonymization of the samples, in which case the relationship from your personal information (which reveal your identity) and your biological samples and associated clinical data would be eliminated. Effects of anonymity and cancellation could not be extended to research that had already been done.

If you wish to withdraw your consent or request the anonymization of your samples, you must request it in writing by contacting Dr. Mayka Sanchez at the following address: Department of Basic Sciences. Faculty of Medicine and Health Sciences, International University of Catalonia (UIC), Josep Trueta, s/n, 08195 Sant Cugat del Vallès, Barcelona, Spain.

Information about the research results. We will send you information if you wish to receive it

If you expressly request it, you may be provided information on investigations that have used your samples and the overall results of the investigation, except in case of cancellation or anonymization.

The methods used in biomedical research are often different from those approved for clinical practice, so you should not consider them as clinically valuable. However, if these investigations provide data that could be clinically or genetically relevant to your health or that of your family, you will be notified if you deem appropriate. If information obtained is relevant to your family, it will be up to you to decide whether or not to tell them. If you want to receive relevant information arising from the project, you must indicate so by marking in the box at the end of this document.

If you do not wish to receive this information, please note that the law states that if the obtained information is necessary to prevent serious harm to the health of your biological relatives, a welfare expert committee shall consider the case and decide whether to inform them or their legal representatives.

Please ask the person who gave you this information any questions you may have, now or in the future, in connection with this agreement.

We appreciate your generous collaboration with the progress of science and medicine. Thus you are working to overcome disease and help many current and future patients.

INFORMED RESEARCH CONSENT FOR USING AND CONSERVATION OF BIOLOGICAL SAMPLES AND CLINICAL DATA FOR BIOMEDICAL RESEARCH
RESEARCH PROJECTS ON IRON METABOLISM AND HEMATOLOGICAL DISEASES

Name and surname of the patient……
ID number or passport……. Age.....

Reporting person (medical doctor, nurse) and Center/Hospital's name
……
ID number or passport …….

If you have understood the information given to you, you have resolved any questions you might have and you decide to collaborate with this research project outlined in the above terms, please **read and sign** this form below.

The undersigned authorizes UIC to incorporate biological material in the registry of human biological samples as part of the research project referred in this document. These projects have the required approval of the competent Research Ethics Committee. This authorization is granted after being verbally informed and having read the enclosed information.

Please remember that your participation in this study is voluntary; you can withdraw from this study at any time, without explanation and with no impact on your health care.

I confirm:

1. I authorize the donated biological material and associated clinical information to be used for research on the terms contained in the "Information document for the Patient"
   YES☐ NO☐

2. I wish to be notified by a counselor committee or a medical geneticist specialized about information concerning this research that is truly relevant and applicable to my health or my family health
   YES☐ NO☐ Telephone or E-mail……

3. I authorize the storage of samples during the study period and also sending samples and relevant clinical information to collaborators and experts from these research projects listed in the "Information document for the Patient"
   YES☐ NO☐

PATIENT	REPORTING PERSON (medical doctor, nurse)
Signature	Signature

LEGAL REPRESENTATIVE WHEN THE PATIENT IS UNDER AGE

Please, check as appropriate
☐ Father ☐ Mother ☐ Guardian or legal representative

Signature ID number or passport

.....(city), ... 20..... (date) ***Copy for UIC***

BIOMEDICAL RESEARCH PROJECT INFORMED CONSENT REVOCATION

If you have understood the information given to you, you have resolved any questions you might have and decide to **revoke the cooperation with this project**, please read and sign this form below.

Patient:

I, ...
with ID number/passport ..... nullify the informed consent.
Date:.....(day).....(month) .....(year) and I do not wish to continue the voluntary donation to this research project, which I completed today.

☐ I REQUEST THE ELIMINATION OF THE SAMPLE ONLY
☐ I REQUEST THE ELIMINATION OF PERSONAL DATA ONLY. The sample will be irreversibly anonymised and may be used in research projects.
☐ I REQUEST THE ELIMINATION OF MY DATA AND SAMPLE

Signature:

..... (city),.....20 ..... (date)

Guardian or legal representative of the patient:

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Date: .....(day).....(month)..... (year) and I do not wish to continue the voluntary donation to this research project, which I completed today.

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ID number or passport……. Age.....

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LEGAL REPRESENTATIVE WHEN THE PATIENT IS UNDER AGE

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..... (city),.....20 ..... (date)

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Signature:

..... (city),.....20 ..... (date)

Copy for the patient