Patientendaten

Klinik / Station / Praxis

UNIVERSITÄTS KLINIKUM FREIBURG
Institut für Immundefizienz
Centrum für Chronische Immundefizienz

Patient Information and Consent form for Patients

Donation, Storage and Use of Biological Materials and Collection, Processing and Use of Data of the CCI Biobank, Medical Center - University of Freiburg

Information

Dear Patient, dear parents,

The Center for Chronic Immunodeficiency (CCI) is asking for your consent to collect biological materials from you and/or your child for the purpose of scientific research. The collected samples will be stored in a special biomaterial storage facility, the CCI-Biobank, at the Medical Center - University of Freiburg.

Biomaterials here refer to blood, tissue biopsies from diagnostic or operative procedures, such as stool, urine, saliva, and hair as well as other body fluids or cells. The CCI-Biobank is located at the Medical Center - University of Freiburg. The Biobank is a storage facility for human biomaterials linked with selected information, such as medical data. The responsible ethics committee has reviewed this project.

The examination of human biomaterials and the analysis of resultant data is an important instrument of medical research. Therefore, we ask you, as we ask our patients, whether you are willing to provide samples and information for the purpose of research. Your participation is voluntary. No disadvantage will arise from your unwillingness to grant consent or the withdrawal of your consent at a later stage.

The following contains information about the aims of the CCI-Biobank and the procedures and measures to ensure the protection of your personal data. We hope the information provided offers you a sound basis to reach a decision.

If you have any questions do not hesitate to ask your treating physician or the physician who provided you with this information.

1. Aims of the Biobank

The CCI-Biobank serves to promote immunological research. Biomaterials linked to selected donor data are stored on a long term basis in the Biobank and made available for medical research towards improvement in prevention, recognition and treatment of diseases. A disease of the immune system is either suspected or has been confirmed in your case or in the case of your child. The scientific investigation of your samples will help us to better understand your immune system. Storage of the samples will facilitate their use to address medical research questions in the future and therefore help in understanding this disease and other diseases of the immune system.

2. What does the project entail?

Patients with immune defects as well as healthy donors (e. g. family members) are invited to donate samples to the CCI Biobank. If you as a patient with an immune defect wish to provide biological specimens (blood, tissue, stool, urine, saliva, hair as well other body fluids and cells) to the CCI-Biobank, collection of the samples will take place in the course of medically necessary investigation and treatment. Samples collected are primarily tissue and body fluids that are obtained for the purpose of medical investigation and treatment and would be otherwise not needed or destroyed. With your consent, your physician will transfer these samples, linked personal information and medical data to the CCI-Biobank. If medically justifiable an extra tube of blood (or additional tissue samples) specifically destined to the CCI-Biobank is drawn from adult patients. Collection of these additional samples will take place during routine blood tests, biopsies, or operations. As the CCI-Biobank also stores samples, such as saliva, urine or stool, which are collected non-invasively, for certain other specified diseases, you might be asked if you would like to provide samples for this purpose as well.

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3. How will biomaterials and data be used?

Biomaterials and linked data are stored for an unlimited period of time in the freezers and the databank of the CCI. Investigations are carried out by scientists of the CCI or scientists from institutions that collaborate with the CCI. These investigations include characterization of hereditary material (genetic material, genome) through genome sequencing with current sequencing methods and methods that will be developed for this purpose in the future. Transfer of samples and data to scientific partners of the CCI takes place exclusively in encrypted form and according to relevant data protection regulations (see section 5). Transfer of samples and data to unauthorized third parties is ruled out. You should not sign the consent statement and select "No" at the end of this document if you are not satisfied with the use and storage duration of the samples described above. Your samples and data will not be deposited in the CCI-Biobank and you will not be asked for consent again if you decline consent.

What personal benefits or risks are incurred from contribution to the CCI-Biobank

Donation of biomaterials does not entail any additional health hazard for you. The only biomaterials used for the CCI-Biobank are samples collected for anticipated diagnostic or therapeutic measures which would otherwise be disposed of or samples collected non-invasively such as urine, stool and saliva. An additional risk arises in collection of materials specially intended for the CCI-Biobank (for instance additional blood tubes or additional tissue biopsies). Accordingly, information will be provided through separate standardized clinical information sheets on the respective invasive procedure.
Unfortunately, we cannot provide compensation for donated samples. You will not be involved in research endeavors with a commercial aim. Your consent involves waiver of commercial rights (particularly patents) to the samples donated, the data resulting from their investigation and the copyrights of research results. The samples deposited at the CCI-Biobank are considered property of the CCI-Biobank. With your consent you grant the CCI-Biobank authority to process and use your data.

Collection, storage and transmission of data from your biomaterials in research projects carry confidentiality risks (e. g. identification) particularly regarding information on your hereditary material. These risks cannot be fully excluded and increase when multiple data can be linked to each other. The risk of confidentiality breach is even greater when you yourself publish your genetic data on the internet (as in ancestry research). The CCI-Biobank assures you that all technically feasible measures to protect your privacy will be undertaken, and that your samples and data will be transferred only to projects that can demonstrate application of adequate data protection procedures.

5. Who has access to your biomaterials and data and how are they protected?

Your biomaterials and data will be stored in the CCI-Biobank according to standardized quality-controlled and secure conditions. Biomaterials and data are stored indefinitely and made available on demand for medical research purposes. State of the art technology is employed to protect data from unauthorized access. The CCI-Biobank provides biomaterials and data only for medical research projects that are examined and judged in ethical and legal terms by an independent ethical commission.

a. Samples are encrypted - pseudonymized - before they are examined, stored or/and transferred. Each patient and participant receives an identification number which is then used to identify samples and test results. The data record is then coded anew (double encryption) and saved. The encryption list containing the identification numbers and the linked personal data (name, date of birth) is kept separate from the CCI-Biobank in another database of the Medical Center-University of Freiburg. Only certain approved staff of the CCI-Biobank has access to this list. Transmission of data to operating researchers takes place exclusively with the identification number precluding exposure of personal information. Tracing of data to your person by a third party is ruled out. All persons who can access these data are obliged to maintain confidentiality and are under obligation of medical discretion. Publication of scientific research only takes place in anonymous form, i. e. in a form that precludes identification of your person.

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b. Twice encrypted biomaterials and medical data can be transferred on demand and after fulfillment of predetermined criteria to other universities, research institutions or industry, including abroad, for the purpose of medical research. Other countries may employ different levels of privacy protection (EU-countries within the reach of the EU GDPR, non-EU countries with an adequacy decision of the EU-commission/appropriate safeguards or countries without an adequacy decision/appropriate safeguards), and hence data transfer can bear certain risks of privacy protection. Data as well as medical records can be linked to other databases under given circumstances as long as legal requirements are fulfilled.

c. Biomaterials and data transferred to a third party can only be used for the determined research purpose. Recipients are not allowed to transfer biomaterials and data further. Biomaterials that are not used are returned to the CCI-Biobank or are disposed of.

6. Will the CCI-Biobank contact you again?

The CCI-Biobank might contact you again at a later point in time to complete information or request specimens. A second contact is an opportunity to update your consent and adapt it to other partner databanks or to communicate to you and/or your family physician medically relevant findings or information. You might be requested to reveal this information to other entities (e. g. before conclusion of an insurance contract). Please place the appropriate mark in your consent statement if you do not wish to be contacted again.

7. You have the right to withdraw consent

Your agreement to contribute to the CCI-Biobank is fully voluntary. You will not be at a disadvantage by refusing to take part. You may also restrict data processing for an unlimited period of time (Art. 18 GDPR) or withdraw your consent at any point in time without justification (Art. 21 GDPR). Withdrawal of consent does not entail any negative consequences at all. In case of withdrawal of consent you are free to choose whether your biomaterials and associated data should be destroyed or further anonymously used for research purposes. However, completed research and publications can no longer be reversed or withdrawn and stay legal. An association of genetic material with your person through other sources cannot be completely ruled out despite withdrawal of consent.

8. Which further rights do you have concerning your data?

The EU-General Data Protection Regulation (EU-GDPR) ensures your personal rights and privacy and enables more transparency and your active involvement. This regulation covers the activity of the CCI-Biobank. The internal processes of the biobank follow the guidelines of the EU-GDPR and ensure safety of data processing. The EU-GDPR comprises extended duties of information: According to Art. 13 and 14 EU-GDPR we have the duty to inform you about the general data protection rights specified in the GDPR as well as the data safety precautions at the University Medical Center Freiburg. You can find this information (in German) on our homepage (www.uniklinik-freiburg.de) under the link "Datenschutz" and as written information at the following places: Patient registration and waiting room of the outpatient clinics and other central places within the University Medical Center Freiburg. On demand, a copy of your personal data processed in the biobank can be sent to you free of charge (Right of access by the data subject, Art. 15 GDPR). If necessary, you can rectify the stored data (Right to rectification of inaccurate personal data, Art. 16 GDPR). The right to erasure (Art. 17 GDPR), to restriction of processing (Art. 18 GDPR), and the right to object to processing of personal data (Art. 21 GDPR) were already explained in section 7: in case of data processing on the basis of an informed consent you have the right to object with effect in the future at any time. The legality of the processing until the time of revocation remains unaffected. Please contact the responsible person at the CCI-Biobank (see below) for any requests concerning data safety or withdrawal of consent to CCI Biobanking.

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9. In case of any further questions please ask:

Treating physician _____ Tel: _____

Leader and responsible person of the CCI-Biobank:
PD Dr. Alexandra Nieters (Head Clinical Research Unit (CRU) CCI)
Tel +49 761 270-78150, E-Mail: alexandra.nieters@uniklinik-freiburg.de

Data protection officer of the University Medical Center Freiburg:
Universitätsklinikum Freiburg, Datenschutzbeauftragter
Agnesenstraße 6 - 8, 79106 Freiburg
E-Mail: datenschutz@uniklinik-freiburg.de

If you think that your personal data were processed unlawfully you have the right to complain at a controlling institution (Art. 77 EU-GDPR).
Here you find a list of the controlling institutions:
https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

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Consent form for Patients

I declare that I was sufficiently informed, verbally and in writing, about the purposes of the CCI-Biobank and the possibility of proposed scientific investigations. All my questions in relation to this project were satisfactorily answered. I am aware that my contribution to this project is voluntary and that I can withdraw my consent at any point in time without justification and without any disadvantages. I agree to grant my biomaterials and data to the CCI-Biobank of the Medical Center - University of Freiburg and consent to their use for medical research purposes as described in the information sheet. I hereby grant ownership of biomaterials to the CCI-Biobank. I agree to transfer samples and associated data to another institution provided comparably high data protection procedures as in the CCI-Biobank are guaranteed.

I declare my consent to participate in CCI Biobanking under the above specified conditions ☐ **no** ☐ **yes**

I also agree to genetic investigations ☐ **no** ☐ **yes**

I agree to being contacted again at a later date:

- for the collection of biomaterials and information ☐ **no** ☐ **yes**
- for feedback of medically relevant results ☐ **no** ☐ **yes**

I consent that samples and data are used for research purposes in Germany and abroad after double encryption, and agree to their transfer to collaborating research partners abroad. ☐ **no** ☐ **yes**

I agree to the use of collected samples and data for commercial purposes including in the pharmaceutical industry and for patent development at the Medical Center-University of Freiburg after double encryption. ☐ **no** ☐ **yes**

I have received a copy of the patient information sheet and the patient consent statement. Original versions remain at the CCI-Biobank.

Date	✕ Patient's signature (aged 14 and older)	Consenting doctor's signature and stamp

In the case of minors and incapacitated persons:

I am acting as authorised representative/ legal representative/ carer

Representative name, first name (Please print in block letters)	✕ Representative's signature
2nd representative name, first name (if required) (Please print in block letters)	✕ 2nd representative's signature

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