

Hilda Biobank Freiburg

Information für Jugendliche von 12-16 Jahren – Englisch

Information for adolescents aged 12-16 years

on the donation, storage, and use of biomaterials as well as the collection, processing and use of data for scientific purposes

Dear Patient,

we are committed to ensuring that all patients to receive the best possible diagnosis and treatment. We can achieve this goal only by constantly improving research in medicine and advising the treating doctors according to current scientific knowledge. For this reason, we work closely together with doctors and researchers from various work groups, evaluate courses of disease and perform research in the laboratory. This project requires a biobank in which specimens and associated data are collected from patients and stored.

We use the term “biobank” to mean a large collection of specimens of human fluids, such as blood, and tissue, such as skin. The collected specimens in the biobank are material which is no longer needed and which was taken for necessary examinations and is now left over. Instead of discarding the remaining material, it can be stored in a biobank and used for medical research. The specimens are associated with information about a patient and his/her disease (e.g. age, sex, nature of the disease and examination findings). This information is known as data.

The Hilda Biobank Freiburg was named after the Grand Duchess Hilda von Baden (1864-1952), whose commitment to sick children led to the founding of Freiburg’s first paediatric hospital. The Hilda Biobank is a partner biobank in the centre for biobanking at the Universitätsklinikum Freiburg (FREEZE-Biobank, <https://www.uniklinik-freiburg.de/freeze-biobank.html>) and specialises in biobanking for children and adolescents. Biomaterials from the Hilda Biobank may also be stored at other partner biobanks at the University Medical Centre.

A prerequisite for the storage of your specimens and data is that you agree to the collection and use of your specimens and data. In this information form, we explain many important things about the biobank to you. You may decide whether you wish to participate and grant us your consent. By doing so, you would provide your leftover specimens, which are normally discarded, for future research projects. Your participation is absolutely voluntary and you may withdraw your consent at any time without this resulting in any disadvantages for you. You can take your time to discuss everything with your parents and/or your family before you make a decision.

1. What are the objectives of our biobank?

With the Hilda Biobank, we hope to better understand the causes of diseases in children and adolescents. We would also like to help develop modern diagnostic methods and find new drugs to combat special diseases. The collected specimens and data will be stored for an indefinite period in the biobank and used exclusively for medical research. Since we cannot yet say exactly which research projects are useful in the future, the specimens may also be used for investigations which will only be developed in the future.

Biobanks are important for modern research

2. Which specimens and data will be collected from me?

The fluids and bodily tissues which are taken in any case as part of your treatment by your doctors and which are left over after the testing for a diagnosis are collected. These are, for example, fluids such as blood, bone marrow, cerebrospinal fluid, urine, or tissue such as skin, muscle, oral mucosa, hair roots, and this depends on what you are undergoing testing for. We may ask you to give us additional materials, such as blood or bone marrow. However, you do not need to undergo another examination for this. We would take the additional specimens only during examinations which are performed in any case and if it is medically safe for you and without any risks.

Specimens will be collected during necessary examinations



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In addition to the bodily materials, information about your disease, referred to here as “data” for short, is of particular importance. The stored data include, for example, your age, your sex, the nature of your disease. All persons who gain access to your medical data are obligated to maintain confidentiality and must follow applicable data protection laws. If your data are linked with the specimens, they are given a special code number. As a result, researchers who receive the data together with your specimens cannot trace them back to you personally. More information about the protection of your specimens and data is also available under item 8.

Data on your disease will be linked with your specimens

3. How will my biomaterials and data be used?

Specimens received in the laboratory of the biobank will be either stored directly (for example, urine) or processed, preserved, and then stored (for example, blood). The collected specimens and data will be used exclusively for important issues in medical research. To do this, special tests and analyses will be carried out on the specimens and data. These may also include test methods which are only developed in the future. Genetic testing, that is, testing of the hereditary material, may also be performed on your specimens. Under certain circumstances, testing of your entire hereditary material may also be performed.

Your specimens and data will be used for medical research

4. Forwarding of my specimens and data to other researchers

To answer important research questions, the Hilda Biobank Freiburg works together with other researchers domestically and abroad. These are national and international associations/networks which want to improve the research of diseases in children and adolescents and the diagnosis and therapy of affected patients by means of scientific investigations. These include, for example, the Deutsche Gesellschaft für Kinder- und Jugendmedizin (DGKJ) and many other professional societies of the individual areas of paediatrics. The Freiburg Kinderklinik is also actively involved in various European reference networks (ERN) for the standardisation and harmonisation of the diagnosis and therapy of rare diseases. Cooperation with companies in the pharmaceutical industry is also possible, for example, to develop new drugs. However there are strict requirements and rules here which the companies must comply with.

National and international researchers conduct joint research projects

A precondition for the forwarding of specimens and data is that the research projects undergo an expert review beforehand by the ethics committee. The specimens and data can be forwarded to researching doctors, scientists and bioinformaticians only if the planned investigations are considered to be useful.

Research projects undergo an expert review beforehand

Of course, if your specimens and data are forwarded to other researchers, only the code will be indicated and not your name or other information from which it could be discovered that the specimens come from you.

5. What are the risks to me if I participate?

Health-related risks

If you decide to donate your leftover specimens to the Hilda Biobank Freiburg, this does not involve any additional risk to your health. Only bodily materials which are taken during planned examinations in any case are used for the biobank.

No health-related risks

Other risks

Whenever data from specimen material are collected, stored or transmitted for research projects, there may be a risk that confidential information is disclosed or obtained. It may happen, particularly in the case of data which concern your hereditary material, for example, that you will be identified, that is, the specimen will be linked to you personally. These risks can never be completely excluded and increase as more and more data are linked. We will do everything possible according to the current state of the art to protect your privacy. This also includes that we will provide your specimens and data for other projects only if the researchers also comply with the data protection regulations and the ethics committee has approved the project.

A risk with confidential information cannot be completely excluded



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6. What benefits do I have by participating in the biobank?

It is not expected that you will have any personal advantage or benefit for your health by donating your specimens and data. The analysis is intended exclusively for research. In general, the investigations do not involve individual specimens but rather a number of different specimens from different patients. Therefore we will not inform you of the use of your specimens and data and the results obtained from them. However, with your participation, you may also help other patients who benefit from the development of new diagnostic methods and therapies.

With your participation, you can help other patients in the future

In individual cases, it is possible that a researcher will by chance obtain a result which is of great importance for you and your health. This may be, for example, knowledge about other diseases or a predisposition to another disease. In this case, we will contact your treating doctor.

In the event of important results, we will inform your doctors

7. Do I have to participate in the biobank and can I change my mind?

Participation in the biobank is completely voluntary. It is up to you, together with your parents, to decide whether or not to participate. You will not receive any money for your participation, not even if researchers – with your specimen or data – devise new methods and develop drugs which are then sold. If you decide not to participate, this will not have any effect on your further medical treatment. You may revoke consent at any time, without stating your reasons. We call this “withdrawal.” This will not result in any disadvantages for you. In this case, please discuss this with your family and your doctors so that we are aware of it.

Participation is voluntary and you may end it at any time

If you withdraw your participation in the biobank, your data will be blocked from use by the biobank as of this point in time. Your specimens will be either destroyed or anonymised (this means that no one can associate your specimens with you any longer). We cannot undo any results which have already been obtained up to this point in time. These remain unchanged. Your medical data in the hospital will also not be deleted. These data are a part of your medical records and must be kept for legal reasons.

8. Who has access to my specimens and data and how will they be protected?

All specimens and data in our biobank will be given a letter and number code. We call the code “pseudonym.” This means that, when we use your specimens and data, we do not use your name or other personal information, instead only this code. Therefore, researchers who use your donated specimens for their investigations do not know that these are your specimens. Only a few employees of the biobank who are obligated to maintain particular confidentiality know the decoding for your specimens. This is important, for example, if you withdraw your consent and we have to once again allocate your specimens to you.

Your personal data will be replaced by a code

Scientific results which were obtained with the aid of your specimens and data may also be published in medical journals. However, in doing so, you will remain fully unknown (anonymous).

9. What should I know about my rights regarding the protection of my data?

The rights regarding the protection of your data are described in the European data protection law. Since we also collect data from you within the scope of the biobank, we want to give you additional information about your rights regarding the protection of your data.

Rights regarding the protection of your data

The contact person listed on page 1 is responsible for the processing of the data in the Hilda Biobank Freiburg. According to the law, you may request information about your stored data. You may also request the correction of incorrect data, a transfer of data you provided, as well as deletion of the data or restriction of the processing of these data. If this should apply to you, please get in touch with the contact person listed on page 1.



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Biomaterials and data may also be forwarded to researchers in countries outside of Europe. In some cases, the level of data protection in these countries may be lower than in European countries and the data there may thus be less protected. More detailed information about this and also about possible risks are described on the homepage of the Universitätsklinikum Freiburg (<https://www.uniklinik-freiburg.de/footer/navigation/datenschutz.html>). However, your specimens and data will be forwarded in these special cases only if you have consented to this in the informed consent form by ticking the corresponding box.

Forwarding of specimens and data to countries outside of Europe

If you should have any questions about data protection, you can also directly contact the data protection officer of the Universitätsklinikum Freiburg (e-mail: datenschutz@uniklinik-freiburg.de). You also have the option of contacting a data protection supervisory authority at any time. A list of supervisory authorities in Germany is available at:

https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

10. Will I or my family be contacted again?

It is possible that we will want to contact you or your family again at a later point in time to inquire about additional information. If you do not consent to this, please tick the corresponding box on the informed consent form.

We may contact you again

Once you have reached the age of 18, you yourself can decide on the further use of your specimens and data. We will therefore try to contact you within one year after you have reached majority age. If necessary, we will also utilise publicly accessible sources of information to obtain your current contact data.

11. Whom can I contact if I have questions?

If something is not clear to you, you can get in touch with your treating doctors at any time or also the Hilda Biobank Freiburg:

Biobank Coordination
Kinder- und Jugendklinik
Universitätsklinikum Freiburg
Breisacher Straße 62
79106 Freiburg
zkj.hilda-biobank@uniklinik-freiburg.de



Hilda Biobank Freiburg

Information und Einwilligung für Jugendliche von 12-16 Jahren – English

Information and consent for adolescents aged 12-16 years

on the donation, storage, and use of biomaterials as well as the collection, processing and use of data for scientific purposes

Einwilligungserklärung Biomaterialnutzung

The use of my specimens and data for scientific use in the Hilda Biobank Freiburg has been explained to be verbally and I received written information. All of the questions I asked were answered to my satisfaction and I had enough time to think about my participation. I am also aware that comprehensive genetic testing may be performed on the specimens, where applicable.

I hereby consent to the donation of my specimens and data to the Hilda Biobank Freiburg. I consent for my specimens and associated data, as described in the information form, to be used for medical research projects.

I know that participation in the Hilda Biobank Freiburg is voluntary and that I may withdraw my consent at any time, without stating any reasons, without this resulting in any disadvantages for my treatment.

In addition, I have been informed that, in the event of important health-related events, my treating doctors will be contacted and that I will be contacted again once I reach legal adult age.

Einwilligungserklärung Datenschutz

I consent for the Universitätsklinikum Freiburg to collect and store data about myself and my health and to provide these data together with the specimens in encoded (pseudonymised) form for medical research projects. The specimens and data may be used for an indefinite period for medical research purposes, until revoked.

I consent for my specimens and associated data to be forwarded to cooperating researchers domestically and abroad for purposes of medical research. The countries have a comparable level of data protection. Under certain circumstances, biomaterials and data may also be forwarded for research projects in countries outside of the European Union (EU). This is only permissible if the EU data privacy preconditions for this purpose are met.

I have been informed that I may withdraw my consent with regard to the Hilda Biobank Freiburg at any time and without stating any reasons. In the event of withdrawal, the remaining specimens and data will be destroyed or deleted or anonymised, upon my request. In addition, my rights within the scope of the EU GDPR have been explained to me. I am aware that data from analyses which have already been performed can no longer be removed.

I have received a copy of the information and informed consent form.

Declaration of participation in the Hilda Biobank Freiburg

(Name of patient is in the header of the informed consent form)

I hereby declare my voluntary consent to participate in the Hilda Biobank:

Yes No

I consent to be possibly contacted once again at a later point in time for purposes of obtaining further information:

Yes No

I consent to the release of biomaterials and data to recipients in non-EU countries who may have a lower level of data protection:

Yes No

Date

X

Patient signature

I have conducted the informational discussion and obtained consent.

Date

Physician's stamp

Signature of physician

