

## **Patients' Information / informed consent for the research project of the Medical University Graz:**

### **Provision of tissues, blood samples and other body fluids for research purposes and the development of new diagnostic methods, preventive measures and therapies**

Dear Patient!

#### Introduction

The scientific examination of tissues, blood samples and other body fluids in combination with symptoms of diseases is today one of the most important premises for a better understanding of the reason for and the progression of diseases as well as for the development of new methods for diagnosis, prevention and treatment. For this, cells or other elements are isolated from medical samples, proliferated and examined according to microscopic, biochemical, immunological and molecular-biological methods. Also gene-analytical methods are used. (All these methods are scientific techniques with which the various chemical and biological processes in the human body and its cells, respectively, are explored and can be better understood.)

Such examinations are only possible if patients are willing to provide medical samples.

**We invite you to participate in the above listed research project. Your written consent to the participation is a premise for the realization of this research field. Please, read the following text carefully in addition to the detailed discussion with medical experts and do not hesitate to ask questions.**

#### Actions within the scope of the research project:

- Should blood samples, other body fluids or tissues be taken during the already planned examination in the course of the diagnosis and treatment of your disease, it is intended to collect and archive the elements of those medical samples that are not directly needed for your further medical care in a so-called Biobank without being bound to a time limit. Furthermore, these samples can be used for further research in combination with the collected data concerning the disease. This Biobank is the property of the Medical University of Graz and independent from companies.  
In no case are more or other tissues removed than are absolutely necessary for the diagnosis and therapy of the existing disease, respectively. If other scientific projects of the Medical University of Graz require additional interventions, you will be informed separately. Only if a routinely planned blood sample is taken then up to 20 ml blood could additionally be taken from you.
- In order to find correlations of the research results and your disease, the Medical University of Graz is allowed to gather information of the course of disease from your general practitioner, your attending doctor or other hospitals where you have been treated.

- Together with the data concerning the course of your disease the research results are encoded and stored in the database. The encoded samples are stored as well. "Encoded" means that no third person except the attending doctors and the directly involved personnel of the Biobank can relate the medical samples, the diagnostic findings as well as declarations of disease symptoms and life style with you personally. All people that have access to these samples and data are liable to legal requirement concerning confidential medical communication. Protection against the access of unauthorized persons is secured. The head of the Biobank of the Medical University of Graz bears the responsibility for storing and, if necessary, destroying data and samples.
- Research is basically carried out at the Medical University of Graz and in collaboration with other research centers. The analyses of encoded samples or encoded data can also be performed in national and international cooperation with external partners (e.g. other research centers, companies).
- Your medical samples and data are meant to lead to scientific findings of reason, course, therapy and prevention of diseases and finally to the development and quality control of new diagnostic aids and methods. If applicable the encoded research results may be published in scientific papers, used for training doctors and used scientifically as well as commercially, e.g. for patenting, in collaboration with other companies and persons.

Regarding your provision of medical samples, diagnostic findings as well as declarations to disease symptoms and life style no financial compensation or shareholding in any possible commercial utilization of the research results is foreseen.

An individual feedback on information and research results that have been obtained from your medical samples is only foreseen in case it includes medically relevant information for you. However, you can decide on obtaining or not obtaining this information.

The scientific scheme and this patient's information / informed consent were certified and approved by the responsible ethics commission. Future research projects that are planned to implement samples and/or data stored in the Biobank are only carried out upon a new project-related and approved statement of the ethics committee. Only coded samples and coded data will be transferred from the Biobank to the research projects.

Your consent to the above is optional and does not affect the diagnosis and treatment of disease destined for you. No additional costs arise from the participation in this research project for you. You can disapprove of the consent or withdraw your accepted consent in written or oral form without giving reasons. In this case any connection of the samples obtained from you as well as data and your person will be deleted irrecoverably. On request, the samples are removed from the Biobank and destroyed. For further information or for the cancellation of your consent please contact the coordination of the Biobank of the Medical University of Graz, Stiftingtalstraße 24, A-8010 Graz (Tel. 0316-385-72716).

**Please, only sign the informed consent if:**

- you have completely understood the kind and process of the research project,
- you agree to participate and
- you are aware of your rights as a participant of this research project.



*Patientenetikette aufkleben  
(falls vorhanden)*

## Informed Consent

I, ..... born on .....,  
have read and understood the patient's information consisting of 2 pages after I have been made aware of its contents. With my signature I declare to participate in the research project "*Provision of tissues, blood samples and other body fluids for research purposes and for the development of new diagnostic methods, preventive measures and therapies*".

In the course of an informational conversation I was informed in detail and in a very comprehensible way about the essence, relevance and importance of the research project by Mr./Mrs. (MD) ..... All my questions were answered sufficiently and I had enough time to decide on this. At the moment I do not have any further questions.

With my signature I give my consent that I leave the samples that are no longer needed for my medical treatment to the Medical University of Graz for the respective research project. If a routinely planned blood sample is taken then **up to 20 ml blood** can **additionally** be taken from me.

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

Furthermore, I permit the Medical University of Graz to use the findings concerning my person and the collected data regarding disease symptoms and life style for the relevant research project.

Beside the data that are available at the regional hospital (LKH Graz)/University Hospital, this includes **medical data** collected for diagnostic or therapeutic reasons **of other institutions as well (general practitioner, medical specialist and other hospitals)**.

In this regard I authorize the Medical University of Graz to ask for these data directly at the listed institutions.

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

The handling of the samples and/or data is subject to the Data Protection Act and the Genetic Engineering Act. In case of possible circulation of samples and/or data as well as possible publication of data of this research project I am not mentioned by name.

I have received a copy of this patient's information and informed consent. The original remains at the Medical University of Graz.

My participation in this research project is voluntary. I can cancel my consent at the Medical University of Graz any time without giving reasons and without having to face any disadvantage for my medical treatment.

I wish to be informed about relevant medical research results concerning me personally or my direct descendants.

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

.....  
(date and patient's signature)

Before Miss/Mrs./Mr. .... signed this consent I informed her/him in detail and declare I have not put pressure on her/him.

.....  
(date, name and signature of the responsible medical doctor)

*Many thanks for participating!*

