

Donor's information Informed consent

**to participate in the development of data and sample collection at the Biobank
at the Medical University of Graz**

**Provision of human samples and associated data for research purposes and
the development of new methods for diagnosis, prevention and treatment**

Dear donor,

Introduction

The scientific study of human samples (such as tissue, blood and body fluids) in conjunction with medical records, is now one of the most important requirements for a better understanding of the causes and courses of diseases, the development of new methods for diagnosis, and the prevention and treatment of these diseases. All the methods used for the analysis of human samples are scientific techniques that are employed to research and better understand the various chemical and biological processes in the human body and cells. For this purpose, components (such as cells or proteins) are isolated from human samples and studied with microscopic, biochemical, molecular biological, genetic analytical methods or can be further processed and cultured.

Such studies are possible only if you as the donor agree to provide your medical samples and data for this purpose. The Biobank Graz is a centralized, company-independent service unit owned by the Medical University of Graz which has taken over the storage and provision of samples and data for research.

We cordially invite you to participate in the development of sample and data collection at Biobank Graz. Data, stored at Biobank Graz comprise sample related data which are linked to a minimal dataset (person related data). You can find an exact explanation of person related data on the Biobank Graz homepage (see table 1). The condition for the implementation of this project is your written consent. Please carefully read the following text. If you have any questions, please contact your treating doctor or the Biobank Graz contact (see table 1).

Actions within the framework of the Biobank Graz project:

With your agreement, you allow us to store your medical samples that are obtained as part of your visit for examination or treatment at the Medical University of Graz / LKH-Univ. Klinikum Graz and which are no longer required for further medical care. These samples will be held without a time-limit at the Biobank Graz. If you are a patient at an external facility (independent specialist, general practitioner, other public and private clinical facilities, rehabilitation center) and your samples are sent to the LKH-Univ. Klinikum Graz or to the Medical University of Graz for further diagnostic purposes, you allow us to store personal data (minimal dataset), sample related data and residual material that is not used for further diagnosis at the Biobank Graz without a time limitation. Furthermore all personal data, that is necessary for your treatment will be kept in the hospital information system and can be used pseudonymised (explained below) together with your samples for research.

Use for research may also occur immediately, without prior storage. With your current consent, you allow us to use samples and data that were already available at the

Medical University of Graz / LKH-Univ. Klinikum Graz or will be collected in the future. This means that samples that were obtained during previous stays at the Medical University of Graz / LKH-Univ. Klinikum Graz or external facilities as part of your diagnosis and / or treatment and are no longer necessary for your further medical diagnosis and / or treatment, can also be stored in the Biobank Graz and can be used for research.

On no account will more tissue be removed from you than necessary for the diagnosis or treatment of your existing disease. Only in the context of provided blood samples additional blood, to a maximum of 20 ml (approximately 4 teaspoons), could be taken. However, this only applies if blood is collected in cooperation with LKH-Univ. Klinikum Graz, otherwise no additional blood is collected at external facilities.

Your samples are kept pseudonymised (explained below) at Biobank Graz. Through this encoding, only authorized persons have access to your personal information. When handling data, these persons are subject to the EU General Data Protection Regulation (GDPR) as well as the Austrian adaptation regulations in the currently valid version.

The responsibility for storage of the samples lies with the management of Biobank Graz.

A distinction is made between the following data that is collected and processed about you in the course of treatment and research activities:

- 1) "Personal" data by means of which you can be directly identified (e.g. name, date of birth, address, pictures).
- 2) "Pseudonymised" data in which all information that allows direct conclusions to be drawn about your identity is replaced by a code (e.g. a number) or made unrecognizable. This means that the data for third parties can no longer be assigned to your person without the use of additional information and without disproportionate effort.
- 3) "Anonymized" data, which can no longer be traced back to your person.

The research with your medical samples and data will be conducted at Medical University of Graz or in other national and international (academic and non-academic) research institutions. This includes a global sample and data transfer, which is done in a pseudonymised form without disclosing your identity.

Your medical data and samples should lead to scientific knowledge of the causes, course, treatment and prevention of diseases and are eventually used for development and quality control of new diagnostic tools and methods, as well as for the training of health care professionals.

The prerequisite for the use of samples and / or data from the Biobank and, respectively extended data from the hospital information system for research purposes is an approval by the ethics committee of the Medical University of Graz.

Research results in an anonymous form will be published in scientific literature and can be further utilized scientifically or commercially by the Medical University of Graz or by the above-mentioned research institutions for example for patenting.

For the provision of medical data and samples, no financial compensation or involvement in a possible commercial exploitation of research results, is intended. However, the Biobank can charge the research partners an expense allowance for the provision of the samples and data.

Your consent is entirely voluntary and has no influence on the diagnostics and treatment of your condition. By participating in developing the sample and data collection of Biobank Graz there are no costs to you. You personally may refuse to consent without giving reasons or revoke your already given consent personally at any time without giving reasons in a written or oral statement. In this case, your samples and data stored at Biobank Graz will no longer be provided for research. For further information or withdraw of your consent, please contact the management of the Biobank Graz (see table 1). For general information concerning privacy protection contact the data security officer (see table 1).


The development of the Biobank Graz for the provision of human samples and associated data for research purposes as well as this donor information / consent form have been reviewed and approved by the Ethics Committee of the Medical University of Graz.

Please only fill in the consent form:

- if you have fully understood the nature and procedure of participating in the development of sample and data collection of the Biobank Graz and
- if you are aware of your rights to participate in the development of sample and data collection of the Biobank Graz

The following contacts offer you the opportunity for further information:

Table 1: Sources of information

Information	Contacts
Biobank Graz homepage	https://biobank.medunigraz.at
Minimal dataset	https://biobank.medunigraz.at/en/for-patients/informed-consent
Explanation of terms	https://biobank.medunigraz.at/en/for-patients/informed-consent
General questions about participating in the development of the Biobank Graz	Tel: 0316-385-72716
Revocation of the declaration of consent	Neue Stiftingtalstraße 2/B/2; 8010 Graz E-Mail: biobank@medunigraz.at Tel.:0316-385-72716
Patient info clip	https://biobank.medunigraz.at/en/#c52487 
Data protection	E-Mail: datenschutz@medunigraz.at

Thank you for your participation!

Barcodeetikette aufkleben

Informed Consent



I, born on, and thus of legal age at the present time, have read and understood the donor information for the participation in the development of Biobank Graz to provide human samples and data for research purposes and the development of new methods for diagnosis, prevention and treatment.

I had enough time to carefully read this donor's information and I am informed about the nature, significance and implications of this sample and data collection within the Biobank Graz. Currently I do not have any further questions. Should any questions arise I am informed about the contacts from which I can obtain information. My participation is voluntary.

By handling the samples and / or data, the provisions of the Data Protection Act and the Genetic Engineering Act are respected. By a possible dissemination of the samples and / or data, or for any publication of research results, I will not be named. I have received a copy of this donor information and consent, a further copy remains at Biobank Graz.

With my signature I agree that I transfer the ownership of my medical samples, which are no longer needed for my treatment, to the Medical University of Graz. I also agree that my pseudonymised data will be used for research projects carried out over the Biobank Graz research project. In addition to data collected at LKH Univ.-Klinikum Graz and Medical University of Graz, this includes pseudonymised data collected for diagnostic or therapeutic reasons from other institutions (general practitioner, medical specialist and other hospitals). I may withdraw consent without giving reasons at any time at Biobank Graz, without thereby creating a disadvantage for my medical care.

Yes, I agree

No, I don't agree

.....
Date

.....
Signature of the donor



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