

Donor's information / Informed consent for the Biobank Graz research project of the Medical University of Graz:

Provision of human samples 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, and for the development of new methods for diagnosis, prevention and treatment of these diseases. All 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 or genetic analytical methods. Such studies are possible only if you as donor agree to provide your medical samples and data for this purpose. At Medical University of Graz, Biobank Graz is a centralized, company-independent service unit owned by Medical University of Graz and which has taken over the storage and provision of samples and data for research.

We cordially invite you to participate in the aforementioned Biobank Graz research project. Condition for the implementation of this project is your written consent. Please carefully read the following text as an addition to a detailed discussion with medical experts and do not hesitate to ask questions.

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 Medical University of Graz / LKH Univ.-Klinikum Graz and which are no longer required for further medical care, without time-limit in Biobank Graz and to use them together with your medical, non-personally identifiable, information for research. Use for research may also occur directly without prior storage. With your current agreement, you also allow us to use samples that are already available at Medical University of Graz / LKH Univ.-Klinikum Graz or which may be collected in the future at this site.

On no account will more tissue be removed from you than is necessary for the diagnosis or treatment of your existing disease. Only in the context of routinely provided blood samples could additional blood, to a maximum of 20 ml (approximately 4 teaspoons), be taken.

Your samples are kept in coded form (pseudonymised) at Biobank Graz. Through this encoding, staff of Biobank Graz have no access to your personal information. All

persons who have access to these samples and coded data are subject to confidentiality.

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

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, of course in an anonymous form. Tracing back to your person is excluded.

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.

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

Future research projects that are planned to use samples and/or data stored in Biobank Graz 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 Biobank Graz to the research projects.

For the provision of medical data and samples no financial compensation or involvement in a possible commercial exploitation of research results, is intended.

Your consent is entirely voluntary and has no influence on diagnostic and treat of your condition. By participating in this research project there are no additional costs for you. You may refuse to consent without giving reasons or revoke your consent at any time without giving reasons in a written or oral statement. In this case, your samples will no longer be provided for research. For further information or withdraw of your consent, please contact the management of the Biobank Graz, Medical University of Graz, Neue Stiftingtalstraße 2 / B / 2, A-8010 Graz (Tel. 0316-385-72716 or biobank@medunigraz.at).

This Biobank Graz research project and this donor information / consent form has been reviewed and approved by the relevant Ethics Committee.

Please only fill in the consent form:

- if you have fully understood the nature and procedure of the research project and
- if you are clear about your rights as a participant of this research project.

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 Biobank Graz research project: "Provision of human samples for research purposes and the development of new methods for diagnosis, prevention and treatment.

In the course of a clarification talk, I was informed in detail and understand about the nature, meaning and scope of the research project. All my questions were answered adequately and I had adequate time to decide. Currently I have no further questions. My participation in this research project 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. The original remains in 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 Med Uni Graz. I also agree that my coded clinical data will be used for the Biobank Graz research project. This includes coded medical data collected for diagnostic or therapeutic reasons of other institutions (general practitioner, medical specialist and other hospitals). I may withdraw without giving reasons at any time my consent at Biobank Graz, without thereby creating a disadvantage for my medical care.

<input type="checkbox"/> Yes, I agree	<input type="checkbox"/> No, I don't agree
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Date

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Signature of the donor

I have discussed in detail this declaration with the donor before signing and confirm that I have exercised no pressure.

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Date

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Name of the responsible, professionally competent person

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Signature of professionally competent person

Thank you for your participation!



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