Information on the further use of biological material and/or health-related data for biomedical research.

Dear Patient

For purposes of diagnosis or treatment, fluids (e.g. blood, urine, or other bodily fluids) or tissue samples are often collected from patients and analysed. Such fluids and tissue samples are known as biological material. In many cases, not all of the biological material is used for diagnosis and treatment purposes. The remaining material, and also your health-related personal data (e.g. age, sex, genetic data, blood test results, health status, conditions, treatments, etc.), is very useful for biomedical research.

Although biomedical research has made substantial progress in recent decades, there are still many areas where knowledge of the causes, detection and treatment of diseases could be further improved for the benefit of the patients concerned. Numerous research projects in these areas can only be carried out today if biological material and health-related data are available.

We would therefore ask you to grant the <<institution>> permission to use the biological material obtained from you and/or your health-related data, if appropriate, for biomedical research.

Your consent is voluntary and may be revoked at any time. Your decision will not affect your medical treatment. Please take as much time as you need to make your decision.

To help you make your decision, the most important information is summarised in this booklet.
What does my consent imply?
If you give your consent, your biological material, genetic data and health-related data can be made accessible to biomedical research. This means that your biological material and health-related data can be passed on to researchers or to another institution for research purposes, under the conditions specified below.

As long as it is not revoked, your consent applies to all future projects. Accordingly, you will not be informed each time your biological material and health-related data are used in research projects or passed on to another institution.

What does health-related data comprise?
The term “health-related data” covers all the data in the patient record – e.g. data on possible risk factors and the results of clinical, imaging or laboratory (chemical) tests and genetic analyses obtained by the physician investigating your condition. It also covers data concerning the course of disease and the response to treatment.

How are my biological material and health-related data protected?
The institution undertakes to store your biological material securely. Access to your biological material and health-related data is clearly regulated. Only authorised and clearly defined persons at the institution have access to the uncoded personal data and to the coding key.

What does coding mean?
Coding means that all the details that could identify you (e.g. name, date of birth, etc.) are replaced by a code, so that it is not possible for data to be linked to your person by anyone who does not know the code. Within the << institution >>, the data can also be accessed in uncoded form by authorised and clearly defined persons. The coding key always remains in the institution.

How will my biological material and health-related data be used for research?
All research projects involving the use of your biological material and/or health-related data have to be approved in advance by the responsible ethics committee. The << institution >> can only pass on the biological material and health-related data to researchers in coded form.
The researchers may work at institutions such as hospitals, universities or industrial companies either in Switzerland or abroad. However, the country in question must have legal requirements for data protection which are at least equivalent to those applicable in Switzerland.
What happens if the results of research are relevant to my health?
In many cases, the results of research are not relevant for the individual patient. However, if a study does yield results which are directly relevant to your health, and preventive or therapeutic measures would be possible, you have a right to be informed of this. If you do not wish to receive this information, please inform the person indicated at the end of this document accordingly.

What happens to the results of research involving my samples and health-related data?
The results of research projects are generally published and may help to improve the treatment of future patients.

Will I benefit financially if the results of research lead to the development of a product?
No. The results of research projects may also contribute to the development of commercial products, such as new drugs. But research involving biological material and health-related data is just a small component in this process. This means that you have no claims with regard to commercial exploitation or patents associated with your biological material and health-related data.
The law prohibits the << institution >> from making a profit from the transfer of biological material as such. However, the costs incurred (storage, laboratory activities and transport) may be charged to researchers.

Do I have a right to access my personal data?
Yes. You can contact the << institution >> at any time to obtain information on all the data concerning your person which it holds.

Do I have a right to revoke my consent?
Yes. If you subsequently revoke your consent, from that point onwards, your biological material and health-related data can no longer be used for research purposes. You do not need to give any reasons for revoking your consent. Any revocation should be addressed to: << institution >>, <<address including e-mail>>.

Who should I contact if I have any further questions?
If you have any queries or wish to find out more, please contact your physician, who will be able to provide further information.
The contact details of the << institution >> are as follows: <<Name and contact details of the institution>>

By permitting the use of your biological material and health-related data, you are making a valuable contribution to biomedical research. Many thanks!
Declaration of consent to the further use of biological material and/or health-related data for biomedical research (biobanks)

Patient’s name and first name: Date of birth:

I hereby consent to the further use, for research, of biological material collected from me for purposes of diagnosis or treatment, together with information on my condition. Before being used for specific research projects, the biological material will be coded by the clearly defined persons responsible at the <<institution>>. This means that the persons participating in a research project will not know who the biological material is derived from.

In addition, for research projects within the <<institution>>, I consent to my health-related data (e.g. my patient record) being made available in uncoded form. Access will be restricted to a clearly defined group of persons. My data will be coded as rapidly as possible. For persons outside the <<institution>>, it will never be possible to link the data to my person.

My biological material and data may only be passed on in coded form to other institutions in Switzerland or abroad for research. It must also be guaranteed that the same data protection requirements are applicable. Each research project must be approved by the responsible ethics committee.

I confirm that:

- I have received the information sheet associated with this consent form (version V-2.0).
- I have been adequately informed about the further use of biological material and health-related data for biomedical research.
- I have had the opportunity to ask questions, and they were answered to my satisfaction.
- My consent is voluntary and, in particular, I will not be advantaged or disadvantaged in any way, whatever my decision may be.
- I know that, as a donor, I have the right to be informed of results which are directly relevant to my health.
- I am aware that I can revoke my consent at any time, without stating my reasons.
The <<institution>> is managed by <<Name >>. For queries or suggestions, the <<institution>> may be contacted as follows: <<address, telephone number, e-mail of the institution>>.

Place, date, legally valid signature of the patient or authorised representative.

Place, date, legally valid signature of the person obtaining the informed consent.