Explanatory notes on the declaration of consent with additional blood sample
Make a contribution to medical research

Dear Patient

For many years now, medical research has allowed Insel Gruppe doctors and scientists to contribute to medical progress and thus to the health of the population. Over recent years, this has resulted in considerable advances in the prevention, diagnosis and treatment of diseases.

Although research has made great progress, there are still many areas where further improvement would be possible in terms of the causes, detection and treatment of diseases for the benefit of affected patients. Research projects in these areas can only be carried out because large numbers of patients are willing to provide health-related information or biological material.

Fluids (such as blood, urine, liquor and other bodily fluids) or tissue samples are often taken from patients and investigated for purposes of diagnosis or treatment. These fluids and tissue samples are called biological material. It is often the case that in this process not all of the biological material is used for diagnosis or treatment purposes. However, this residual material and your health-related data (e.g. age, sex, genetic data, blood values, state of health, diseases, therapies, etc.) are extremely valuable for medical research.

For this reason we are asking you to give your consent to help us to develop medical research further by permitting Insel Gruppe to use biological material taken from you as well as your health-related data for medical research.

To ensure that we also have adequate material available for new research projects and are able to carry out high-quality studies, we would also like to ask for your consent to take one additional blood sample from you.

This leaflet summarises the most important information so that you can make a decision.

Your consent is voluntary. You can revoke your consent at any time. Your decision will not affect your medical treatment in any way. Take all the time you need to make your decision.
Part A:

Explanatory notes on the use of biological material and health-related data for medical research.

What does your consent mean?

If you give your consent, your biological material, genetic data and health-related data may be made accessible to medical research. This means that, under certain conditions, your biological material and health-related data may be passed on to Insel Gruppe researchers or researchers at another institute for research projects. Your consent applies to all future projects. This means that you will not be informed each time your biological material and/or health-related data are used in research projects.

What do health-related data comprise?

Health-related data are all data from the patient file, such as data on possible risk factors, results of clinical, imaging or laboratory investigations and genetic investigations, that are collected during the assessment of your disease. They also include data that describe the course of the disease and the reaction to any therapies that are carried out.

How are your biological material and health-related data protected?

Insel Gruppe places the utmost importance on adherence to legal requirements. Your biological material and data will thus be stored in a secure manner. Access to your biological material and health-related data is clearly regulated. Only few clearly designated individuals in the institute have access to uncoded personal data and to the code. Otherwise, the health-related information and biological material are only available to researchers in coded or anonymised form.
What does coded or anonymised mean?

**Coded** means that all details that could identify you (e.g. name, date of birth, etc.) are replaced by a code so that persons who lack access to the code can no longer identify you. The code remains in Insel Gruppe at all times.

**Anonymised** means that all details that could identify you are irrevocably deleted. Your data can no longer be used to identify you.

Are there requirements for passing on biological material and health-related information to other research institutes in Switzerland and abroad?

Yes, the requirements are extremely clear and regulated by Swiss law. It must be guaranteed that at least the same data protection requirements exist at the research site as in Switzerland.
**What happens with the research results?**

You have a fundamental right to information. However, the biological material and health-related data will be used for studies where the results of individual persons are not analysed in detail. These results may contribute towards improvement in the treatment of future patients. This means that you will not be informed of the results of individual research projects where your material or data are used.

**Will you receive a financial benefit if the research results lead to a product?**

A financial benefit is excluded by law. Under certain circumstances the results of the research projects may also contribute to the development of commercial products, for example to the development of new drugs. However, research with biological material and health-related data only represents a small component in this process. For this reason, you do not have any claim to commercial utilisation or to patents connected to your biological material and health-related data. Applicable law also prohibits Insel Gruppe from making a profit by passing on biological material.

**Do you have the right to see your data?**

You may contact Insel Gruppe at any time in writing to obtain information about all the personal data held about you.

**Can you revoke your consent?**

Yes, definitely. You can revoke your consent at any time without giving any reason. Your biological material and health-related data may no longer be used for research purposes from this point onwards.

Please send any revocation of consent to:

Insel Gruppe AG
Directorate of Teaching and Research
Declaration of consent
CH-3010 Bern
e-mail: einwilligungserklaerung-forschung@insel.ch
What happens if you do not sign the consent form?

If you do not give your consent, Insel Gruppe is only entitled to use your data for purposes of quality assurance and research as follows:

– Further use of your genetic data and biological material (e.g. residual material from blood) in anonymised form.
– Further use of your non-genetic data in coded form.
– Your anonymised biological material and/or your anonymised genetic personal data and your coded health-related personal data may also be passed on to third parties for research purposes.

However, if you also do not agree to the evaluation of your anonymised biological material or your data for research purposes, you can lodge your objection at any time. In this case, please contact the attending physician. Your objection will not affect your further treatment in our hospital.

Would you like to know more?

If you have any questions or require further details, please contact your physician or the address below.

Insel Gruppe AG
Directorate of Teaching and Research
Declaration of consent
CH-3010 Bern
Telephone +41 31 632 58 45
e-mail: einwilligungserklaerung-forschung@insel.ch
Part B:

Consent for additional blood sample for Liquid BioBank Bern

To achieve significant research results, researchers require access to large numbers of high-quality samples. This is why it is of paramount importance to Insel Gruppe that an additional blood sample can be taken from patients in addition to existing samples. You must give separate consent for this additional blood sample.

How will your sample be used?

The storage and passing on of your sample are governed by the same standards that apply to health-related information and medical samples. You can, in particular, refuse to give or revoke your consent at any time without giving any reason. In addition, the management and passing on of samples are defined in regulations authorised by the cantonal ethics commission.

Why is an additional blood sample required?

Compared to investigations carried out for your treatment, research has different requirements for the quality of samples. It is of particular importance that all samples used in a study are processed in the same manner. How a blood sample is taken, transported and stored affects the quality of the sample. The additional blood sample means that these processes can be standardised and documented. Quality assurance and storage are guaranteed at Liquid BioBank Bern. This means that Liquid BioBank Bern can provide various research projects with samples of uniform and consistent quality.

Why is additional information (height/weight/ethnic group) required?

Your blood sample is extremely valuable for research. In addition to existing health-related data, this additional information helps to categorise the samples. This means that your sample can be made available to those research projects that will derive the greatest benefit from it.
When will the blood sample be taken?

The blood sample will be taken during your stay in hospital as an in-patient or during an out-patient appointment. You will not need to attend a specific appointment for the BioBank blood sample.

What is a biobank?

A biobank is a collection of samples, amassed for studies or general research purposes. Data on the sample itself and on the donor are recorded for each stored sample.

What is the purpose of Liquid BioBank Bern?

Over recent years, samples have predominantly been collected specifically for individual studies. This has meant that valuable material from trial subjects was only available to a limited circle of researchers. The aim of Liquid BioBank Bern is to establish a collection of samples that can be made available to various research projects. This will increase the benefit of individual samples for research and reduce time and costs for medical research.

Where can you find further information about Liquid BioBank Bern?

Liquid BioBank Bern (LBB) belongs to Insel Gruppe. LBB was established to provide effective facilitation of biomedical research in particular and to support it through the provision of patient samples of outstanding quality in an international comparison. Its aim is to improve prediction, prevention, diagnosis and therapy in human medicine. In addition, the collected samples and data can be used to investigate fundamental mechanisms required for the understanding of diseases.
To find out more about Liquid BioBank Bern, please visit our website: www.biobankbern.ch.

By giving your consent, you are contributing to the further development of medical research. Thank you very much.
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