Information on the measures for the sampling of biological material and/or collection of data connected with minimal risks and burdens, for further use in research

Dear Patient,

While biomedical research has made great strides in recent decades, there are still many areas where our knowledge in terms of cause, detection and treatment of diseases can be further improved for the good of the patient. Numerous research projects in these areas today can only be carried out if biological material and health-related data are available.

<<Type of material or data>> are sampled or collected for the purpose of conducting research projects. The sampling of this material, and the collection of this data, which happens in addition to any diagnostic or therapeutic measures, will mean only a minimal burden for you.

We request that you allow us to sample and collect <<type of material or data>> from you for further use in research.

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

This brochure summarises the key points necessary to allow you to reach a decision.
What does my consent mean?
<<Type of material or data>> will be sampled from you using <<method>> and collected via a questionnaire. The biological material and data thus obtained can be made available for 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 you do not withdraw your consent, it will apply to all future projects. This means that 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.

How does the biological material get sampled?
<<Sampling method>>.
The Ethics Committee on Research must approve the procedure beforehand.

What measures are taken to protect my biological material and my data?
<<Institution>> commits to the safekeeping of your biological material. Access to your biological material and your data is strictly regimented. Only authorised and explicitly designated persons who are part of the institution have access to your unencrypted personal data and to the encryption key.

What does “encrypted” mean?
“Encryption” means that all identifying information (name, date of birth, etc.) is replaced by a code; persons unfamiliar with the code who do not have access to the encryption key will not be able to draw any conclusions as to your identity. Authorised and explicitly designated persons within <<institution>> will be able to access the data even without encryption. The encryption key will remain in the institution at all times.

How will my biological material and my data be used for research?
All research projects involving the use of biological material and/or your data must be authorised in advance by the ethics committee in charge. <<Institution>> may pass your biological material and health-related data on to researchers in encrypted form only. Researchers may work at institutions such as hospitals, universities or industrial enterprises either in Switzerland or abroad. However, the legal requirements for data protection abroad must at the very least be equivalent to those in Switzerland.
What happens with the research results that are relevant to my health?
In many cases, the research results 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 the right to be informed. If you wish to exercise the right to receive information, you must indicate this on the consent form.

What happens with the research results involving my samples and health-related data?
Research project results are generally published and can lead to improved treatment for future patients.

Will I reap a financial benefit if the research results lead to the development of a product?
No. While the results of these research projects may contribute to the development of commercial products such as new drugs, research involving biological material and health-related data is only a small part of that process. For that reason you have no claim with regard to the commercial exploitation or the patents associated with your biological material and health-related data. <<Institution>> is prohibited by law from profiting financially from passing on biological material as such. However, the researcher may be invoiced for related expenses (storage, lab work, transportation).

Am I entitled to view my personal data?
Yes. You may contact <<institution>> at any time to receive information regarding all the available personal data concerning your person.

Do I have the right to withdraw my consent?
Yes. Once you withdraw your consent, your biological material and your health-related data may no longer be used for research purposes from that point forward. You do not need to provide a reason for your revocation. You can withdraw your consent by contacting: <<institution>>, <<institution’s address including email>>

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

By giving your consent to 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 measures for the sampling of biological material and/or collection of data connected with minimal risks and burdens, for further use in research

Patient's last name, first name: Date of birth:

I hereby consent to biological material being sampled and data being collected from me using <<method>>. The responsible persons at <<institution>>, who are explicitly designated, will encrypt the biological material and the data ahead of their use for individual research projects. This means that the persons involved in a research project will not know that I am the source of the biological material and the data. My biological material as well as my data may be passed on to other, foreign or domestic institutions for research purposes in encrypted form only, and the same requirements for data protection must be guaranteed. Each research project must be authorised by the ethics committee in charge.

I hereby confirm that:

- I have received the information sheet associated with this declaration of consent (version v2.0).
- I have been adequately informed about the procedure resulting from my consent.
- I have been adequately informed about the further use of biological material and data for biomedical research.
- I have had the opportunity to ask questions, and they were answered to my satisfaction.
- My consent is given voluntarily, and I will suffer neither positive nor negative consequences irrespective of my decision.
- 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 have the option to withdraw my consent at any time without stating my reasons.
<<<<Institution>>> is run by <<name>>. <<Institution>>> is available for any questions or suggestions.

<<institution’s address, phone number, email >>

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

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