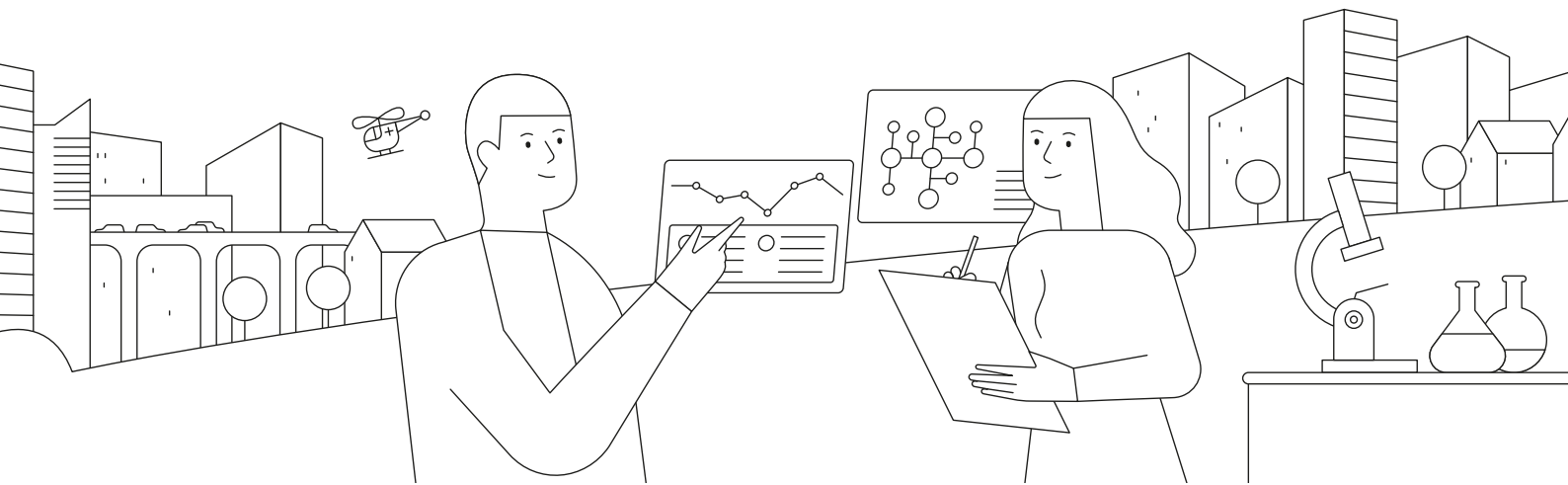


# Participation in research

Information on the use of health data and samples for research purposes and general consent to research



Our ability to diagnose and treat diseases has made considerable progress over recent decades. This has been made possible thanks to the continued efforts of medical research, in which several generations of doctors, scientists and patients have played an active part.

A significant proportion of this research relies on the use of patients' clinical data found in medical files, such as the results of laboratory analyses, medical treatments or genetic predispositions. Any biological material (such as blood, urine or tissue samples) collected during a stay in hospital and which is no longer needed for the patient's care can also be extremely valuable for research purposes.

This document explains how you can contribute to medical progress. It also explains how we protect your data and your rights.

Thank you for your interest and attention.

## How can you contribute to research?

You can make a contribution to research by agreeing that your data and biological samples that are no longer needed can be stored, passed on and reused for research purposes. Data and samples include those that have been collected in the past. They also include any that are collected for your care during current and future stays and consultations at CHUV.

### **Your consent is voluntary.**

It remains in effect for an indefinite period, or until you withdraw it. You may withdraw your consent at any time, without having to give a reason. To do so, you simply need to inform the Research Consent Unit at the address shown on the back of this document.

*If you decide not to participate in research by ticking "NO" for statement A, your clinical data and biological samples cannot be used for research.*

If you do not sign the consent form, i.e. if you do not respond, the law provides that samples and data can be used for research on an exceptional basis subject to authorisation from the relevant ethics committee. It is therefore important for you to make your wishes clear.

### **Your decision will not have any effect on your medical treatment.**

## What happens if you withdraw your consent?

If you withdraw your consent, your data and samples kept for research will be destroyed, subject to legal requirements. They will no longer be available for new research projects. This does not apply to data and samples that have already been used.

## How are your health data and biological samples protected?

Data are stored at the hospital and protected in accordance with the legal requirements in effect<sup>1</sup>. Only authorised hospital staff, such as the doctors in charge of your care, have access to your data and samples in a way that identifies you.

Your biological samples are stored in biobanks. This ensures that your samples are managed correctly and linked to the data contained in your medical file. Samples and data may be used for a variety of purposes, including research. They are subject to safety and quality standards ([www.chuv.ch/consentement-general](http://www.chuv.ch/consentement-general)).

If your data and samples are used for a research project, they are coded or anonymised.

- The term “coded” means that any personal information (for example, your name or date of birth) is replaced by a code. The key that indicates which code corresponds to which individual is kept in complete safety by a person who is not involved in the research project. People who do not have access to the coding key are not able to identify you.
- The term “anonymised” means that the link between the biological material or associated data and the individual is permanently broken. According to the law, data are deemed to be anonymised when they cannot be linked to a particular person without excessive effort. In principle, it is no longer possible to identify the person concerned, though absolute anonymisation cannot be guaranteed. Once the data and samples have been anonymised, it is impossible to prevent their use, even if the person concerned withdraws their consent. It will also not be possible to inform them of any research results that may be relevant to their health. Similarly, anonymised samples or data are not destroyed if consent is withdrawn.

The majority of research projects use coded data, particularly if they might produce results that would be relevant for the health of the people concerned.

You have the same rights to data protection in relation to research as you do for your care, in particular, the right to access your personal information.

## Who can use your health data and samples?

Data and samples can be used by researchers who have been granted authorisation by the relevant Research Ethics Committee. Research projects are carried out in the hospital or in conjunction with other public institutions (such as other hospitals or universities) and private entities (such as pharmaceutical companies) in Switzerland or abroad.

Projects may include genetic analyses for research purposes.

Data or samples can only be sent abroad for research purposes if the data protection conditions in the destination country are at least as stringent as those applied in Switzerland.

\* In particular, the Federal Act on Research involving Human Beings and data protection legislation.

## Will you be informed of research results?

In principle, the research carried out using your samples and data will not reveal any individual information about your health. In rare cases, however, relevant results may be discovered, for which treatments or preventive actions are available. In this case, you would be informed. If you do not wish to receive such information, please contact the Research Consent Unit at CHUV, at the address indicated at the end of this document.

## Will your participation involve any financial costs or benefits?

Your participation will not involve any additional costs for you or your insurance company. The law does not allow any commercial use of data or samples. There will therefore not be any financial benefit for you or the hospital.

## The Genomic Biobank at CHUV (BGC) is a collection of blood samples donated by patients on a voluntary basis.

It was specially created to conduct genetic analyses for research purposes. The BGC links genetic data with the data in patients' medical files. This is a leading resource for carrying out research on developing new treatments and preventive measures.

*If you answered "YES" for the reuse of your data and samples in statement **A**, please tell us whether you are also willing to contribute to the BGC by responding to statement **B**.*

## What does this mean for you in practical terms?

If you consent to contribute to the BGC, a 7.5 ml sample of blood may be taken. If possible, this will be done at the same time as a blood sample needed for your care, to avoid another needle prick. The blood sample is only taken once, even if you stay in the hospital on more than one occasion.

**Your decision will not have any effect on your medical treatment.**

## Where are samples kept?

Samples are coded and stored safely in dedicated freezers at CHUV. The conditions governing access to the samples, their use and transmission are described in the biobank regulations, which can be found on the website indicated on the back of this document.

## What happens if you withdraw your consent?

If you withdraw your consent, the blood sample collected specifically for the BGC is destroyed.

## Is there a charge for the additional sample for the BGC?

No, there is never a charge for samples or analyses carried out for research purposes. They do not involve any additional costs for you or your insurance company.

You can let us know your decision by completing and signing the consent form.

The consent form is in three sections:

- A** Please complete your last name, first name and date of birth, and then indicate whether or not you agree to the use of your health data and samples for research purposes.
- B** If you agree to the use of your health data and samples for research purposes (i.e. you have answered "YES" to statement A), please indicate whether or not you also wish to contribute to CHUV's Genomic Biobank.
- C** Sign and date the form to confirm your decision.

Once you have completed the consent form, please return it to us at the address shown on the back of this document.

If you have any questions or if you wish to withdraw your consent, please don't hesitate to contact us.

By post:

CHUV-Département de la formation et recherche  
Unité consentement général  
Boîte aux lettres N°47  
Rue du Bugnon 21  
1011 Lausanne  
info.cg@chuv.ch

By phone:

021 314 18 78  
Mon-Fri 07:30-12:00 and 13:00-16:00

Further information

**[www.chuv.ch/consentement-general](http://www.chuv.ch/consentement-general)**

# Consent form for use of health data and samples for research purposes

\_\_\_\_\_  
Last name and first name

\_\_\_\_\_  
Date of birth

**A** I consent to my health data and unused biological samples collected during care (outpatient consultations and hospital stays) being kept, passed on and used for research purposes.

YES

NO

If you ticked "YES", please respond to statement B. If you ticked "NO", please go directly to point C.

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**B** I agree to donate an additional blood sample of 7.5 ml to CHUV's Genomic Biobank for genetic analyses for research purposes.

- An additional blood sample of 7.5 ml may be taken during my care at CHUV.
- This sample will be used to carry out genetic analyses for research purposes.

YES

NO

However you respond, please go to point C.

.....

## **C** Confirmation of my decision

I have understood:

- the explanations about the use of my clinical data and biological samples for research purposes, as detailed in the information leaflet;
- that I am free to contact the Research Consent Unit at CHUV using the details shown at the bottom of this form, or a health professional with responsibility for my care at CHUV, if I require any further information or explanations;
- that my personal data are protected and will only be used for research in a coded or anonymised form;
- that my data and biological samples may be used in national and international research projects, in the public and private sectors;
- that projects may include genetic analyses of my samples for research purposes;
- that I may be contacted again if any results relevant to my health are found;
- that my decision is voluntary and has no effect on my medical treatment;
- that my decision is valid for an unlimited period, unless I withdraw my consent;
- that I may withdraw my consent at any time, without having to give a reason;
- that if I tick "NO" for statement A when signing the form, my clinical data and biological samples cannot be used for research purposes;
- that if I do not sign the consent form (no response), the law provides that my data and samples may be used on an exceptional basis if the relevant ethics committee grants special authorisation.



\_\_\_\_\_  
Place and date

\_\_\_\_\_  
Patient's signature

Please do not hesitate to contact us if you have any questions or comments.