Would you like to participate in medical research?

General consent for the use of your health data and biological samples for research purposes

This information brochure explains how you can contribute to the progress of medical research in the context of your medical care undergone at Réseau hospitalier neuchâtelois (RHNe). It offers you some explanations about medical research and the protection of your data and your rights.

Medical research at the RHNe

Our ability to diagnose and treat diseases has progressed significantly over the past few decades. This progress is the result of long-standing medical research in which doctors, scientists, and patients of several generations have been actively involved.

An important part of this research is based on the use of patients' clinical data from medical records: such as laboratory test results, drug treatments, or genetic predispositions. Any biological material (e.g., blood, urine, tissue samples) collected during the hospital stay that is no longer useful for medical care can in turn be extremely useful for research.

In addition to providing medical care, the RHNe actively participates in clinical research, particularly with public and private hospitals and universities as well as private companies. Clinical research is subject to very specific legal and ethical regulations ensuring the respect of your rights and dignity. The law requires your explicit informed consent for any research involving your participation or using your medical data or biological samples.

How can you contribute to research?

You can contribute to medical research by agreeing to have your health data and residual biological samples reused for research purposes, i.e., by ticking the box "YES" on the declaration of general consent. This general consent is both retrospective and prospective, i.e., it includes the reuse of your health data and biological samples that have been collected in the past, but also those that will be collected during your current and future medical care at the RHNe.

Your consent is voluntary.

Your consent remains valid for an indefinite duration or until withdrawn. You are entitled to withdraw your consent at any time without having to justify your decision. To do so, you only have to inform the Clinical Research Coordination of the Medical Direction of the RHNe using the contact information on the general consent form. In this case, your research data and samples will be destroyed, subject to legal requirements. As a result, they will be no longer available for new research projects. This does not apply to data and samples that have already been used.

If you decide not to participate in the research, *i.e., by ticking the box "NO" to the declaration of general consent*, your clinical data and biological samples cannot be used for the research.

However, if you do not sign the consent form, i.e., if you do not provide us with any answer, the law states that the samples and data may be used for research on exceptional circumstances after authorization by the competent ethics committee (LRH art. 34). It is therefore important for you to express your choice explicitly.

Finally, by refusing general consent, you retain the ability to give your consent to a specific research – for example, a drug clinical trial – that may be offered to you during your medical care, at the RHNe or other institutions.

Your decision has no impact on your medical care.

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

The data are stored at the RHNe and protected by the applicable legal requirements. Only authorized employees of the hospital have access to your encoded health data and biological samples, i.e., associated with your personal information (name, address, etc.); for instance, a doctor in charge of your medical care at the RHNe. Your biological samples will be processed by the ADMED Foundation as part of your care at RHNe according to data storage, processing, and protection standards.

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

- The term “coded” means that all personal information (e.g., your name or date of birth) is replaced with a code. The key mapping the correspondence between the code and the individual is kept securely by the clinical research unit team that is not involved in the research project. People who do not have the key are unable to identify you.

- The term “anonymized” means that the link between the biological material or associated data and the individual is permanently lost. According to the law, a piece of data is anonymized when it cannot be linked to a specific person without excessive effort. Yet, absolute anonymization cannot be guaranteed. Moreover, once the data and samples have been anonymized, their use cannot be prevented if the patient withdraws his or her consent. Nor can they be informed of any research findings relevant to their health. Similarly, anonymized samples or data cannot be destroyed in the event of withdrawal of consent.

The majority of research projects use coded data, especially when they can generate results that are relevant to the health of the people participating.

The data protection rights in the context of research are the same as in the context of your medical care. Thus, your participation in medical research through general consent does not expose you to any additional risk.

Who can use your health data and biological samples?

The data and samples may be used by researchers authorized by the competent research ethics committee, usually the Research Ethics Commission of the Canton of Vaud. Research projects are carried out at RHNe and/or in collaboration with other public institutions (such as other hospitals or universities) and/or private entities (e.g., pharmaceutical companies) in Switzerland or abroad.

Sharing data or samples abroad for research purposes is only possible if the data protection conditions in the country of destination are at least equivalent to those applicable in Switzerland (Federal Data Protection Act).

Will you be informed of the results of the research?

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 will be informed (HRA Art. 8). If you do not wish to receive such information, please contact the Clinical Research Unit at the contact information indicated at the end of this document.

Are there any financial costs or benefits associated with your participation?

Your participation will not result in any additional costs for you or your insurance company. The law excludes the commercialization of data and samples. Consequently, there will be no financial benefit for you or the hospital.

The declaration of consent consists of three steps:

Step 1. After completing your last name, first name, and date of birth, indicate whether you accept or refuse the use of your health data and biological samples for research purposes.

Step 2. Sign and date the declaration to confirm your decision.

Step 3. Once you have completed the general consent form, you can either:

(1) Return it by post using the return envelope contained in this letter,
(2) Bring it in person to the admissions secretariat or your doctor's office at the RHNe.

If you have any questions or wish to withdraw your consent, please do not hesitate to contact us using the contact information below:

By postal mail
Réseau hospitalier neuchâtelois - RHNe
Coordination de la Recherche Clinique
Rue de la Maladière 45
2000 Neuchâtel

By e-mail
recherche.clinique@rhne.ch

By phone
+41(0)79 559 53 36

Consent form for re-use of health data and samples for research purposes at RHNe

Name and surname | *Date of birth*

NAME Surname | xx.xx.xxxx

To consent to the use of your data and samples, tick the box "YES". Otherwise, tick the box "NO".

A. General Consent for clinical research at RHNe

I agree that my health data and residual biological samples collected during my medical treatment at the RHNe will be stored, shared and used for research purposes.

☐ **YES** ☐ **NO**

Regardless of your answer to point A, please proceed to point B, date and sign.

B. Confirmation of my decision

I confirm that I have been offered or have had direct contact with a health professional at RHNe to answer all my questions related to this document, and I understand

- The explanations on the reuse of my health data and biological samples for research purposes, detailed in the information brochure.
- That my health data and biological samples are protected and will only be used for research in a coded or anonymized form.
- That my health data and biological samples can be used in national and international research projects, in the public and private sectors.
- That I may be contacted again in the event that results relevant to my health are identified.
- That my decision is voluntary and has no effect on my medical care.
- That my decision is valid indefinitely unless I withdraw my consent.
- That I can withdraw my consent at any time without having to justify my decision.
- That if I tick the box “NO” (Point A) by signing this declaration of consent, my health data and biological samples cannot be used for research.
- That if I do not sign the general declaration of consent, the law stipulates that my health data and biological samples may exceptionally be used if the competent ethics committee gives its special permission.

Indicate the place and date below

Please sign in the box below

If you have any questions or comments, please contact us using the contact details below:

By postal mail
Réseau hospitalier neuchâtelois - RHNe
Coordination de la Recherche Clinique
Rue de la Maladière 45
2000 Neuchâtel

By e-mail:
recherche.clinique@rhne.ch

By phone:
+41(0) 79 559 53 36