

Request to participate in medical research:

Swiss HIV Cohort Study

Dear Sir or Madam,

We are asking if you would like to participate in our research study.

Your participation is voluntary, meaning you do not have to join unless you want to. All information collected in this research is kept private and follows strict data protection rules.

The research is led by Professor Andri Rauch, Inselspital, Bern University Hospital. If you are interested, we can share the results of the research with you.

We will explain the most important points to you and will answer your questions in person. So, that you can already get an idea, here are the most important points upfront. More details will be provided below.

Why are we doing this study?

- Since 1988, the Swiss HIV Cohort Study has been collecting and analyzing information about the health of people living with HIV.
- The goal of the study is to understand more about HIV, other related diseases and the HIV epidemic. We also want to look at the effects of new medicines and treatments, including any side effects. In addition, we study how different social and financial situations as well as genetic factors affect how HIV progresses and how people respond to treatment.
- As part of the research, we examine blood samples and other biological materials (like urine, stool, or saliva), which are taken during regular visits. This helps us understand the biology of HIV and related diseases. Our goal is to improve our knowledge about how the disease works and to move closer to a cure or vaccine for HIV.

What do you have to do if you participate?

- Twice a year, some information about your life situation will be collected. Information from clinical examinations and laboratory results (from routine blood tests) will be collected for the study. All data will be encrypted, collected centrally, and analyzed. Additional blood samples will be taken during routine blood tests to help us better understand HIV and its related diseases, and to study available treatments. The blood samples will also be used to isolate genetic material.
- The study does not have an end date, and your blood samples and genetic material will be stored for an indefinite period for future research.

- You have the possibility to participate in intervention studies that evaluate new health care options for people living with HIV; for this an additional consent is necessary.

What are the risk and benefits?

Benefits

- The information collected from this study is regularly analyzed, and new findings are quickly shared with healthcare providers to improve treatment for HIV.
- The cohort study also enables the planning and conduct of new studies investigating new HIV treatments. By participating, you help improve care for everyone with HIV.

Risks

- From our perspective, there are no known risks. The blood samples are taken as part of your regular blood tests, and you will not need to attend extra visits or have any extra procedures.

By signing at the end of the document, you confirm that you are participating voluntarily and that you have understood the content of the entire document.

Detailed information

1. Purpose and eligibility

In this document, we refer to our study as a *research project*. If you take part in this research project, you are a *participant*.

In this research project, we aim to gain new insights into the course of HIV infection and related diseases and gain a better understanding of the HIV epidemic. We are asking you to participate because anyone over the age of 18 who is living with HIV can take part.

2. General information

- HIV can be successfully treated with modern therapies (called antiretroviral therapies), though there is no cure yet. The antiretroviral therapies prevent the virus from multiplying in the body. However, the success of HIV treatment brings new challenges. The longer life expectancy of people with HIV requires treatment adjustments to account for other conditions like cancer, high blood pressure, or diabetes. Antiretroviral therapies can have side effects, so reducing these side effects and developing simpler treatment options are important goals of the study.
- Despite advances in HIV therapy, an HIV infection can still lead to complications that need to be studied carefully.
- Intensive research is also being done on co-infections, such as viral hepatitis and sexually transmitted diseases.
- Major goals of HIV research are to develop a vaccine and a cure. To achieve these goals, we need to better understand the biology of HIV.
- Genetic factors (such as those revealed by genetic studies) can play a key role in disease progression. People react differently to diseases and medications. Inherited traits (genetic factors) explain many of these differences. We want to study these genetic factors in the hope of finding causes that affect HIV progression, treatment responses, and the occurrence of side effects.
- The Swiss HIV Cohort Study is a national, multicenter research project that has been ongoing since 1988. The research project will continue indefinitely.
- We are conducting this research project according to Swiss law and internationally recognized guidelines. The project has been reviewed and approved by the responsible ethics committee.

3. Procedure

If you choose to participate in the Swiss HIV Cohort Study, the following information will be used from your medical records:

- Information on diseases that occur as a result of HIV or are influenced by HIV.
- Information on diseases that may affect the progression of HIV.
- Results of clinical examinations (such as weight, blood pressure).
- Results of laboratory tests (such as CD4 counts [CD4 immune cells, also known as T-helper cells, are measured to assess whether the immune system is weakened] and viral load [which measures the number of viruses per milliliter of blood]).
- Results of imaging procedures (such as X-rays) or tissue tests (such as biopsies).
- Type of treatment and any possible side effects.

You will also be asked a few brief questions about your HIV risk behaviors and your life circumstances. This survey will take place every six months as part of a regular visit to assess your health, it does not require any additional doctor visits. The data collected comes from routine clinical examinations. During routine blood tests, an additional 10-40 ml of blood will be taken. This blood and any other biological material (such as urine, stool, saliva) will be encrypted and stored for research purposes. This material may be examined later as part of research projects aimed at better understanding HIV infections or diseases influenced by HIV. Additionally, genetic material will be isolated and made available for research projects conducted by the Swiss HIV Cohort Study.

Purpose of the examination of genetic material (genetic studies):

People react differently to diseases and medications. Inherited traits (genetic factors) explain many of these differences. We want to study these genetic factors in the hope of:

- Finding causes that affect the progression of HIV and its complications.
- Understanding why people respond differently to medications and why some experience side effects.

You can decide whether you would like to be informed about any unexpected findings from genetic tests that may be relevant to your health (see Section 8: Results).

Possibility to be part of future randomized low-risk studies using the TwiCs (Trials within Cohorts) design:

For low-risk interventions, such as smoking cessation options or physical activity strategies or similar, we offer a new pragmatic study design: The TwiCs (Trials within Cohorts) design. If you consent to be part of it, we will be able to assign you randomly into the control or intervention group of such a study to test low-risk interventions.

If you are assigned to the intervention, you will receive further information, and you can accept or decline the proposed intervention. If you are assigned to the control group, nothing will happen, you continue the routine follow-up schedule of the cohort, and we will inform you when the study is over. In both cases, you receive best current HIV care as part of the SHCS.

4. Use

If you take part in this research project, it may help you by quickly implementing new scientific findings in daily practice. You may also be asked to participate in future clinical trials within the cohort. In these clinical trials, you may benefit from new treatment options. However, it is also possible that participation will not bring any benefit. The results may be important for other people who have the same disease.

5. Voluntariness and obligations

Participation in the Swiss HIV Cohort Study does not commit you to any treatment, intervention or blood sampling that you would not carry out anyway or that would not be carried out as part of your usual care. You agree to answer a few additional questions every six months at one of the usual visits and to provide us with an additional 10-40 ml of blood.

You are taking part in the study voluntarily. If you do not wish to take part in this research project or wish to withdraw your participation later, you do not have to give any reasons. Your treatment/support is guaranteed regardless of your decision. You can also request at any time that any remaining samples of blood, biological material, and genetic material be destroyed.

If you participate in this research project, you are asked to:

- adhere to the specifications and requirements of the research project specified in the protocol.
- inform your HIV physician about any concurrent treatment and therapy by other physicians and about any medication you are taking.

6. Risks

From our point of view, this study is not associated with any risks. The blood sample is taken as part of a routine blood sample and no additional visits or venipunctures are necessary. You have the option of refusing to answer the study questionnaire at any time.

For women who are pregnant or may become pregnant

You can also participate in the study during pregnancy and while breastfeeding. Irrespective of the study, we recommend that you inform your physician about a planned or actual pregnancy so that the medication can be adjusted accordingly. The physician will discuss the next steps with you.

7. Alternatives

If you do not wish to participate in this research project but are open to the possibility of participating in other research projects, please speak to your HIV physician.

8. Results

There are

1. individual results of the research project that affect you directly,
2. individual results of the research project that arise by chance (so-called incidental findings)
3. objective final results of the entire research project.

Re 1: The HIV physician will inform you during the research project about all new results and findings that are important to you personally. You will be informed verbally or in writing and can then decide again whether you wish to continue participating in the research project.

Re 2: Incidental findings are so-called “concomitant findings”, i.e. findings that were not explicitly researched but were found by chance. These can be, for example, results of genetic analyses or imaging procedures (e.g. magnetic resonance imaging).

In the case of incidental findings, you will be informed if these findings are relevant to your health. This means that you will be informed of such findings if a previously unknown disease has been detected by chance or if a disease that has not yet occurred can be avoided by preventive measures. In this case, you will be contacted by your physician by telephone or in writing and invited to a consultation at which you will be informed of the findings. If you do not wish to be informed about this, please speak to your physician and record this in this document (see consent form).

Re 3: Your physician can send you research results. You also have the option of registering for the cohort newsletter.

9. Privacy and data protection

9.1. Data processing and encoding

For this research project, your personal and health data will be collected and processed, partly in automated form. Your data will be encrypted during data collection. Encryption means that all reference data that could identify you (name, date of birth, etc.) are deleted and replaced by a code. It is not possible to link the data to you without the code, which remains permanently within the hospital or physicians practice where you are being treated. Only authorized personnel have access to this key to ensure your anonymity.

Only a limited number of authorized specialists can view your data in an unencrypted form, exclusively for the purpose of performing tasks within the framework of the research project. These persons are bound to confidentiality. As a participant, you have the right to view your data at any time.

9.2. Data protection and protection of the samples

All data protection regulations are strictly adhered to. It is possible that your data may need to be transferred in encrypted form, for example for a research publication, and may be made available to other researchers. If health-related data/samples are stored on site, this is a database/biobank for research purposes. Data and samples can be encrypted and sent to another database/biobank as part of this project.

As part of national and international research projects, encrypted data and blood samples as well as other biological material can be made available to scientists in Switzerland and abroad who have signed an agreement with us that precisely regulates the use of the data and samples. We would like to point out that the data protection standards applicable in Switzerland are not necessarily guaranteed in other countries. However, the sponsor has taken the necessary measures to protect the rights of participants. Only encrypted data or samples are passed on, and the sponsor contractually regulates the use of the data and samples.

9.3. Data protection for genetic testing

Any collection, storage and transmission of data from your samples in the context of genetic research involves confidentiality risks (e.g. the possibility of identifying you), particularly regarding information about your genetic material. These risks cannot be completely ruled out and increase the more data can be linked together, especially if you yourself publish genetic data on the Internet (e.g. for genealogical research). Information about your genetic material may also be of significance for your relatives or your family planning. The project management will take all measures to minimize these confidentiality risks for you.

9.4. Inspection rights during checks

This research project can be reviewed by the responsible ethics committee and by the project management. The investigator must then disclose your data for such reviews. All must maintain absolute confidentiality.

10. Withdrawal from the study

You can withdraw from the research project at any time. In this case, however, the data and samples collected up to that point will still be analyzed in encrypted form.

In the event of withdrawal, your data and samples will remain encrypted in the project documents. This is for your medical safety. Please check whether you agree to this before participating in the project.

11. Compensation

If you take part in this research project, you will not receive any compensation. There are no costs to you or your health insurance company for participating. The results of this research project may contribute to the development of commercial products. Your participation does not entitle you to any commercial developments (e.g. patents).

12. Liability

If you suffer any harm because of the research project, the Inselspital, Bern, University Hospital, Department of Infectious Diseases, which initiated the research project and is responsible for its implementation, is liable. The requirements and the procedure are regulated by law.

13. Funding

This research project is mainly funded by the Swiss National Science Foundation (SNF).

14. Contact information

If you have any questions about the research project or if any uncertainties arise during or after the study, please contact:

Dr. Marcel Stoeckle, Clinic for Infectious Diseases and Hospital Hygiene, University Hospital Basel, 4031 Basel, HIV Consultation.

Phone: 061 328 75 30

Email: infektiologie@usb.ch

Consent form

1) Written informed consent from the participant to be part of the cohort study

Please read this form carefully. Ask questions if there is something you do not understand. You must provide written consent to participate in the study.

| | |
|---|---|
| BASEC-Number (after submission): | 2023-02080 |
| Title of the research project (scientific and lay language): | Swiss HIV Cohort Study |
| Responsible institution (Project management with address): | Inselspital, Bern University Hospital , Department of Infectious Diseases, Freiburgstrasse 20, 3010 Bern |
| Location of the study: | Infectious Diseases and Hospital Hygiene, University Hospital Basel, Petersgraben 4, 4031 Basel (HIV Consultation, Medical Outpatient Clinic) |
| Investigator at the study site: Surname and first name in block capitals: | Dr. Marcel Stoeckle |
| Participant: Surname and first name in block capitals: Date of birth: | |

- I have been informed verbally and in writing by the undersigned investigator about the purpose, procedures, potential benefits, and possible risks of the research project.
- I voluntarily agree to participate in this research project and accept the content of the written information provided. I have had enough time to make my decision.
- My questions about participating in this research project have been answered. I will keep the written information and receive a copy of my written consent.
- I agree that the responsible professionals of the project management and the ethics committee may view my unencrypted data for auditing and monitoring purposes, while maintaining strict confidentiality.
- If any results (incidental findings) directly affect my health, I will be informed. If I do not wish to be informed of such findings, I will let my doctor know and indicate this in the consent form.
- I know that my health-related and personal data (and samples) will only be shared in encrypted form for research purposes in this research project, including internationally. The sponsor cannot guarantee that data protection will meet Swiss standards everywhere, but they have taken the necessary steps to protect participants' rights. Only encrypted data or samples will be shared, and the sponsor regulates the use of the data and samples by contract.
- I can withdraw from the study at any time without giving a reason. My future medical care will continue as usual. The data and samples collected until that point will still be used for analysis.
- The Inselspital, Bern University Hospital, is responsible for any harm that may occur due to the research project.

If applicable, please check:

I do not wish to be informed about incidental findings.

| | |
|----------------|-----------------------|
| Location, date | Signature participant |
|----------------|-----------------------|

Confirmation of the investigator: I confirm that I have explained the nature, purpose, and scope of the research project to this participant. I assure that I will fulfill all obligations associated with this research project in accordance with Swiss law. If I learn of any information during the research that may affect the participant's willingness to continue, I will inform them immediately.

| | |
|----------------|---|
| Location, date | Surname and first name of the investigator in block capitals: |
| | Signature investigator |

Consent for future use of (genetic) data and biological material in encrypted form:

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|--|------------------------|
| BASEC-number (after submission): | 2023-02080 |
| Title of the research project (scientific and lay language): | Swiss HIV Cohort Study |
| Participant: Surname and first name in block capitals: Date of birth: | |

I allow my encrypted data and samples from this research project to be used for medical research. The samples will be stored in the study site's local biobank and used for future, not yet defined, research projects for an indefinite period.

I understand that the samples are encrypted and that the key is securely stored. The data and samples may be sent to other databases or biobanks for analysis, both in Switzerland and abroad. The sponsor cannot guarantee that data protection will meet Swiss standards everywhere, but they have taken the necessary steps to protect participants' rights. Only encrypted data or samples will be shared, and the sponsor regulates their use by contract.

I agree to this voluntarily and can withdraw my consent at any time. If I withdraw, the data, samples, and genetic data will remain encrypted. I simply need to inform my doctor or the project management, and I do not need to give a reason.

Normally, all data and samples are analyzed together, and the results are published as summaries. If any results relevant to my health are found, I may be contacted. If I do not want to be contacted about such findings, I will let my doctor know and indicate this in the consent form.

If results from the data and samples are commercialized, I have no claim to the profits.
If applicable, please check:

I do not wish to be informed about incidental findings

| | |
|----------------|-----------------------|
| Location, date | Participant signature |
|----------------|-----------------------|

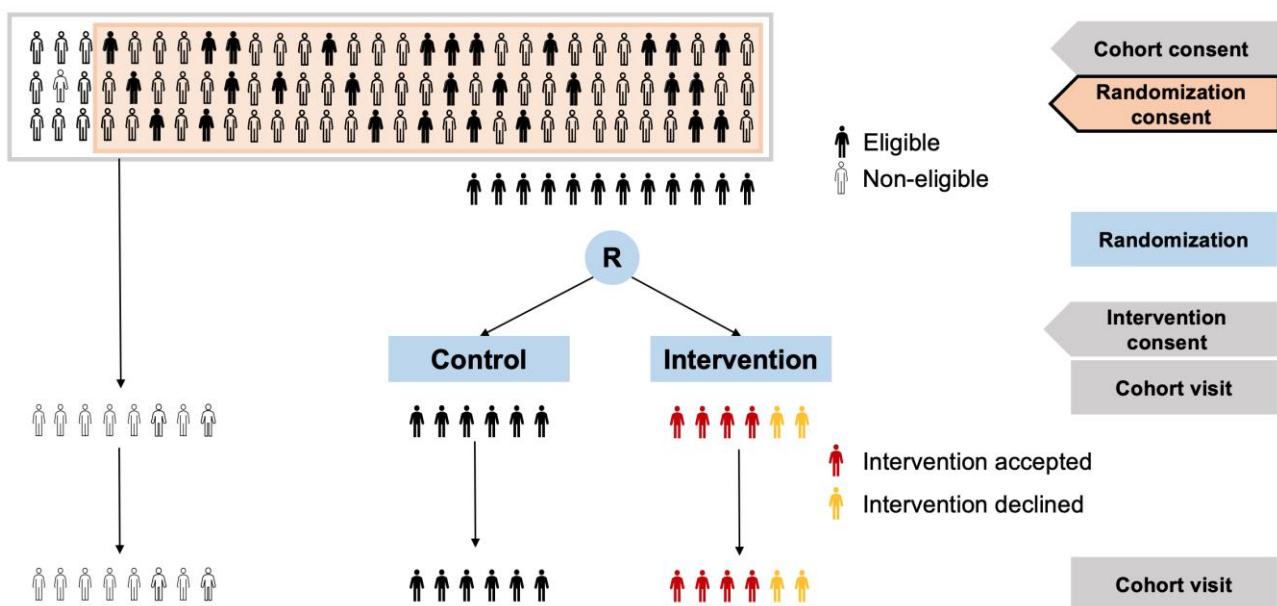
Confirmation of the investigator: I hereby confirm that I have explained to this participant the nature, significance and implications of the further use of samples and/or genetic data.

| | |
|---------------|--|
| Location date | Surname and first name of the investigator in block capitals: Signature of the investigator |
|---------------|--|

Informed consent for participation in studies that use the TwiCs (Trials within Cohorts) design

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|--|------------------------|
| BASEC-number: | 2023-02080 |
| Title of the research project: (scientific and in lay language): | Swiss HIV Cohort Study |
| Participant: Surname and first name in block capitals: Date of birth: | |

I consent to be selected for future randomized studies involving low-risk, pragmatic interventions (e.g. smoking cessation, physical activity, etc.) using the TwiCs (Trials within Cohorts) design. As part of such a study, I will be assigned randomly to an intervention group or to the control group. If I am allocated to the control group, I will not be informed and my treatment within the cohort will not change. If I am assigned to the intervention group, a new health care option will be proposed to me. I can then accept or decline this proposed intervention. If I decline it, I will continue to receive the standard care within the SHCS. I understand that no additional data or biological samples will be collected for these intervention studies.



| | |
|-------------|-----------------------|
| Place, date | Signature participant |
|-------------|-----------------------|

Confirmation of the investigator: I hereby confirm that I have explained the nature, significance, and scope of the research project to this participant. I confirm that I will fulfill all obligations in connection with this research project in accordance with the law applicable in Switzerland.

| | |
|-------------|--|
| Place, date | Surname and first name of the investigator in block capitals |
| | Signature investigator |