Information and consent of patients participating in the Swiss HIV Cohort Study

Dear Sir /Madam

We kindly invite you to participate in the Swiss HIV Cohort Study (SHCS).

The aim of cohort studies is to collect and analyse medical information from a group of individuals with the same disease. Please read the following patient information carefully and, if you agree to participate in this study, please sign the written informed consent.

Summary

Since 1988 anonymized data on the course of HIV infection has been collected and centralized in the **Swiss HIV Cohort Study.**

The **aim of this study** is to improve our understanding of the course of disease and of the care and treatment of HIV infection. Data on antiretroviral therapy and potential side effects are collected and evaluated. Furthermore, the relationship between social and financial factors is studied in connection with the course of disease**.**

Participants in the study are HIV-infected individuals older than 18 years who have given written informed consent. They are followed-up in one of the SHCS study sites (University Hospitals of Basel, Bern, Geneva, Lausanne, Zürich, the Cantonal Hospital of St. Gallen and the Regional Hospital of Lugano, as well as private physicians with relevant experience in the treatment of HIV-infection).

Study structure: Data on the physical examination, laboratory findings, antiretroviral treatment and information on current life style are collected twice a year on standardized forms. All data are collected in an anonymous way in a central database and evaluated. Moreover, within the frame of routine laboratory tests, additional blood samples are taken and stored for future analyses including genetic testing.

The **duration of the study** is indeterminate. Blood samples, biological and genetic material may be stored for an indeterminate time.

How the study is performed

If you decide to participate in the Swiss HIV Cohort Study, the following data will be collected:

- Information on diseases that might occur when CD4 cell counts are low
- Information on diseases that might influence the course of HIV-infection (e.g. hepatitis C)
- Data on physical examination (e.g. weight, blood pressure)
- Results of laboratory tests (e.g. CD4 cell count, HIV viral load)
- Antiretroviral therapy and possible side effects

The data collection is supplemented by a short interview concerning your HIV risk behaviour and current life style. The data collection takes place every 6 months during your usual clinic visit and does not require additional visits. In the framework of your routine blood

examination, additional blood samples (10-40 ml) are taken and stored together with other biological samples (e.g. urin) for future research. Part of this material may be used for genetic analysis for research purposes.

Aims of genetic analysis
Each person may respond differently to diseases and treatments due to inherited characteristics (genetic factors). We therefore aim to investigate genetic factors

- To identify causes that may influence the course of HIV-infection;
- To understand the different response to treatment and the risks of specific side effects

In the case of these genetic analyses resulting in findings of clinical importance you are free to decide whether:
a) □ You want to be informed,
b) □ You do not want to be informed,
c) □ Your treating physician should decide to inform you or not.

Potential benefits
The database of the Swiss HIV Cohort Study is regularly analysed, so that new information can immediately be implemented in to daily practice. Your participation in this study contributes to improving the care and treatment of HIV infection.

Duties of study participants
Your participation in this study does not imply that you receive antiretroviral therapy. If you give your consent, you agree to answer to some questions on your life style, and to allow that blood samples (10-40 ml) and biological material are taken and stored every 6 months. You also agree that genetic analysis may be performed for research purposes.

Potential risks and drawbacks
There are no risks or drawbacks by participating to this study. Blood samples are taken at the time of your routine blood testing without additional risks or visits.

Voluntary participation
Your participation in this study is voluntary. If you do not wish to take part in it, you will not be disadvantaged in terms of your medical treatment. This also applies if you decide to move out of the Swiss HIV Cohort Study after agreeing to participate. You are free to withdraw from the study at any time without need of justification. If you do withdraw, the data collected up to that point will still be used. If you wish, you can request that the stored blood samples and the genetic and biological materials be destroyed.

New findings
Your treating physician will inform you of any new findings that may arise during the course of the study, including findings that could potentially influence your participation in the study. Your treating physician will inform you without hesitation.

Confidentiality
Your personal and medical data will be collected during this study. These data will be anonymised, i.e. given a code. Only anonymous data and coded biological samples will be accessible to national and international experts for scientific evaluation. Within the framework of these analyses, only experts or members of the cantonal ethics committee will be allowed

to access to your non-coded medical data. Throughout the entire study and during these specific examinations, strict confidentiality is guaranteed. Your name will, under no circumstances, be published in reports or publications resulting from the study. The link between your code and your name is kept in the responsible SHCS centre. We are responsible to ensure strict confidentiality in the case of international research collaborations.

If you have any questions regarding your participation in this study, you may contact your treating physician or:
Prof. Dr. med. Enos Bernasconi, Servizio malattie infettive, Ospedale regionale di Lugano, sede Civico (Tel. 091/811.60.21, Fax. 091/811.60.31)

Written informed consent of the patient participating in the Swiss HIV Cohort Study

- Please read this form carefully.
- Please ask if there is anything you do not understand or would like to know.

Study number:	
Title of the study:	Swiss HIV Cohort Study (SHCS)
Sponsor:	*Ospedale Regionale di Lugano, sede Civico*
Study location:	Lugano
Investigator: Name:	
Patient: Name: Date of birth:	☐ male ☐ female

- I have been informed orally and in writing by the undersigned investigator about the study aims, structure, possible (dis)advantages and eventual risks.

- I have read and understood the written patient information sheet of 01.11.2012 provided for the study mentioned above. My questions concerning my participation in this study have been answered in a satisfactory way. I may keep the written patient information sheet and will receive a copy of my written informed consent.

- I have had enough time to make my decision.

- I know that my personal data will be accessible to external institutions only in an anonymised form for research purposes. I agree that experts of the cantonal ethics committee may access my data in the framework of inspections, whilst adhering to the strictest confidentiality.

- My participation in this study is voluntary. I am entitled to withdraw my consent at any time without giving any reason and this will not negatively influence my medical care or treatment.

- In the case of new findings arising from genetic analysis that might have clinical importance I wish:
  - ☐ To be informed
  - ☐ No to be informed
  - ☐ That my treating physician will take the decision whether or not to inform me

- I can request at any time that my blood samples and biological and genetic material are destroyed

Place, date	Signature of the patient

Acknowledgement of the investigator:

I hereby confirm that I have explained to this patient the character, importance and the significance of the study.

I agree to fulfil all duties concerning this study. Should I, at any time during the study, learn about aspects which might influence the patient's willingness to participate in this study, I will inform him/her without hesitation.

Place, date	Signature of the investigator