INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HOPITAL UNIVERSITAIRE DE BERNE
BERN UNIVERSITY HOSPITAL

Information and Informed Consent Form for Patients Participating in the Swiss Transplant Cohort Study (STCS)

Dear Patient

You are foreseen for transplantation and we invite you to participate in the Swiss Transplant Cohort Study (STCS). The study covers all Swiss transplant centres and all transplanted organs including hematopoietic (blood building) stem cells.

Cohort studies collect encoded data about the course of disease in many patients with the same illness. These data are analysed with the objective of gaining knowledge about the progress and complications following transplantation. This in turn enables a unified approach to reporting the results of organ and stem cell transplantation in accordance with Swiss law Art. 20 TxV.

Our duties and your rights within the Cohort Study are described below. Please read this document carefully and, if you are in agreement with its contents, indicate your consent by signing in the place provided.

Summary

Since 01.05.2008 the Swiss Transplant Cohort Study has centrally collected and analysed encoded data from all transplant centres concerning patient progress following transplantation.

The objective is to gain knowledge about the progress and complications following transplantation in all Swiss centres and of all transplanted organs including hematopoietic (blood building) stem cells. Further, the efficacy and side effects of the treatment are captured and the correlation with concomitant diseases, psychological and social factors is analysed. Also the influence of genetic factors on the progress after transplantation, the response to treatment and the occurrence of side effects is examined.

Study participants are all transplantation patients in Switzerland who have given their consent.

For purposes of the study the clinical findings (medical examination) and the laboratory results (blood, urine and biopsy) are captured before transplantation, after 6 months, 12 months and thereafter yearly. All data is encoded, centrally stored and evaluated. During the routine taking of blood samples an extra 45 ml blood sample is taken and stored specifically for STCS evaluation, thus contributing to a better understanding of post transplant progression and therefore to your own care. Further, genetic material can be isolated from the blood sample.

The study period is indefinite.

The study is authorised and supported by the Swiss National Science Foundation and is carried out in compliance with prevailing Swiss law.

Study Procedure
If you decide to participate in the Swiss Transplant Cohort Study (STCS) the following details will be noted: Information about existing illnesses and concomitant diseases, clinical findings, laboratory results, the type of treatment and possible side effects. This data will be supplemented by a short interview about your quality of life and social environment.

The data are captured before transplantation, after 6 months, 12 months and thereafter yearly, within the framework of the normal consultation; no additional doctor's appointments are required. During the routine taking of blood samples an extra 45 ml blood sample is taken and stored for possible later testing which serves to understand better the treatment after transplantation. Information about infectious diseases is continually collected.

Furthermore, genetic material (ribonucleic acids which are required for the synthesis of proteins in the body) is isolated and made available to research projects. The samples are treated in accordance with the Swiss Academy of Medical Science guidelines concerning Biobanks. The reason for studying genetic factors (genetic testing) is that people react differently to disease and medication. Hereditary factors explain many of these differences. Therefore we want to investigate closely to what extent hereditary factors affect progress after transplantation, response to medication and possible side effects.

Possible Benefits
The STCS database is regularly analysed and the resulting findings feedback into daily routine practice. The database also serves as a tool for designing studies covering new methods of treatment and new medications. In participating in the STCS you are making a major contribution to improving the treatment of all people after transplantation. The above mentioned extra examinations and tests involve no cost either to you or your medical insurance.

Possible Risks and Disadvantages
Participation in the STCS does not commit you to any treatment, surgery or venipuncture that would not in any case be required in the normal course of treatment. You agree that during your routine 6 monthly, 12 monthly and thereafter yearly check-ups, you will answer a few extra questions and provide an additional 45ml of blood.

Voluntary Participation
Participation in the STCS is entirely voluntary. You can at any time, and without giving any reason, withdraw your consent to participate without this being in any way detrimental to your further medical treatment. You can also at any time demand that any existing blood samples and genetic material be destroyed. You do not receive payment for participating in the STCS.

Solid Organ Transplantation
According to Swiss law **(**Art. 20 TxV) data relating to solid organ transplantation has to be collected irrespective of STCS participation. If you decide not to participate in the STCS, or to withdraw previously given consent, your data will only be disclosed and reported as required by law**.** You will neither have to provide extra blood or genetic material nor answer any extra questions.

Information about Genetic Factors
For genetic factors with known clinical significance the following applies:
If you wish you may have access to your personal data. Alternatively you may knowingly waive this right even if something relevant for you has been found. You also have the right to anonymization of your data.

The preparation, storage and use of human biological material are performed in accordance with the Swiss Academy of Medical Science guidelines concerning Biobanks (23.05.2006).

For genetic factors with unknown clinical significance the following applies:
The data are encrypted and neither you nor the doctor who is treating you will have any knowledge of the results.

Confidentiality/Data Protection
This study collects personal data relating to you. These data will be encoded. Only people directly involved in your care (Treating Physicians, Study Nurses, Study Co-ordinators and Laboratory staff) have access to your personal data. All these people are subject to professional confidentiality law. To guarantee a complete and correct transfer of the data, which is important for scientific evaluation, chosen employees of the STCS, who are also subject to confidentiality law, may compare the captured data with that of your medical history records. Medical source data may also be viewed by the responsible public authorities, the cantonal ethics commission and STCS specialists. For your protection you explicitly declare that the data may only be used in connection with STCS scientific investigations and only with the consent of the doctors responsible for your care at Inselspital.

Strict confidentiality is guaranteed during and after the study, during the mentioned check ups, and after any possible premature termination of the study. Your name will never be mentioned in any publications emanating from the study. As a study participant you have the right to see your recorded data.

We hope that you have received sufficient information and thank you for your participation.
If you have any questions regarding your rights as a study participant please contact the medical direction at your centre:

Prof. Dr. med. Hans-Peter Marti
Ärztliche Direktion (Aed)
Transplantationszentrum Inselspital
Tel. Data Management: 031 632 00 80 / 031 632 03 42

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Written Informed Consent to Participation in a Cohort Study

Please read this form carefully. Please ask if you do not understand something or if there is something you want to know.

Number of the Study: KEK Nr. 270/07
Title of the Study: Swiss Transplant Cohort Study (STCS)
Place of the Study: Inselspital Bern, Transplantationszentrum
Investigator: Prof. Dr. med. Hans-Peter Marti

Name.....…….....	Forename ……..
M.… F....	Date of Birth……....

I have been informed by the undersigned doctor or the study nurse/counsellor verbally and in writing about the objectives and procedures of the Swiss Transplant Cohort Study (STCS) and about any possible advantages and disadvantages my participation might entail.

I have read and understood the abovementioned patient information from 31.10.2007.
My questions relating to participation in the study have been answered to my satisfaction. I receive a copy of the document that I have signed.

I have had enough time to reach my decision.
I participate voluntarily in this study. I can at any time, and without giving any reason, withdraw my consent to participate without this being in any way detrimental to my further medical treatment.

I can at any time demand that my isolated and stored genetic material be destroyed. I am aware that for genetic factors with known clinical significance I have the right to access my personal data; alternatively I may knowingly waive this right. I am also aware that for genetic factors with unknown clinical significance the data are encrypted and neither I nor the doctor who is treating me will have any knowledge of the results.

I am aware that the right to inspection of my data is broad and covers all other aspects of my personal data. I agree that my medical source data may also be viewed by the responsible public authorities, the cantonal ethics commission and STCS specialists for purposes of testing and monitoring and only in the strictest confidence.

My data may only be used in connection with STCS scientific investigations and only with the consent of the doctors responsible for my care at Inselspital.

Place, Date ……. Signature of the Study Participant……..

Confirmation of the Investigator: I herby confirm that I have explained the nature, significance and importance of the study to this patient. I undertake to fulfil all of my obligations relating to this study. If at any time during the study I become aware of any aspects that might influence the willingness of the patient to participate in the study I will inform him or her immediately.

Place, Date…….. Signature of the Study Doctor…….