Patient information
for the Translational Platform HIV (TP-HIV) of the
German Center for Infection Research

Principal Investigator:

Deputy Investigator:

Treating hospital/physician office:

Dear Patient,

You are being invited to participate in a research project within the framework of the German Center for Infection Research (Deutsches Zentrum für Infektionsforschung (DZIF)). You are currently undergoing treatment for an HIV infection at our hospital/physician office. Your physicians always make an effort to offer you the treatment in accordance with the latest state of medical research. Despite the progress achieved in recent years, HIV cannot be cured to this day. In addition, there are many unanswered questions such as potential long-term effects of the disease or rather the therapy.

You receive this information because your treating hospital/physician office participates in the cohort study "translational platform HIV" (TP-HIV) of the DZIF. Cohort studies are scientific research studies, which are intended to observe patients with specific diseases or even healthy humans over a specific period of time. In the case of this TP-HIV, this observation is based on the collection of data and biomaterial such as blood, urine, or tissue.

The examination of human biomaterial and the analysis of the data derived from it have become an important tool of medical research. Therefore, we are asking all of our patients (including yourself), whether they are ready to provide us with certain body materials and data for research. Your participation is completely voluntary. You will not suffer any disadvantages, should you do not wish to participate or you wish to withdraw your consent later.

If you wish some clarification, please ask your treating physician or your investigator before providing your consent. If you have any questions, you may also contact the principal investigator named on page 1 at a later date.

1. What is the purpose of the translational platform HIV?

Biomaterials and selected data are archived for a long time and provided for research in the data and biobank linked with the TP-HIV. The TP-HIV of the DZIF serves *primarily* the medical research in the field of HIV and particularly with regard to the prevention of new HIV infections, the long-term survival with HIV and a potentially sustainable cure of the HIV infection. You can assume that all samples and information collected during this study are primarily and foremost used for this purpose. In general, we would like to support the TP-HIV but also other valuable research projects dealing with HIP, unless they are not in conflict with the above-referenced purposes. Two reasons should be considered in this context:

A. Future Developments

Research fields are in continuous flux through new results. Therefore, it is impossible to foresee today, the precise need in the future. Therefore, we will provide the information and samples collected within the framework of the TP-HIV in DZIF also for other selected research projects in this field, provided there is a *direct* contextual link with the topic of HIV.

B. Connectedness With Other Research Groups

The DZIF along with other German Center for Health Research conduct projects to research infection. The analysis of biomaterials from many patients helps enable research of rare diseases and complications. Therefore, we would like to include research groups, which are not working on one of the *primary goals* of the TP-HIV in DZIF. In specific cases, these may be research group from the private sector or the pharmaceutic industry. In any case, it is required that the objectives of the research group contacting us seem valuable with regard to patients infected with HIV (see Part 1.A).

The TP-HIV is funded by the German Center for Infection Research, which receives funds from the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung (BMBF)). In addition, part of the recurring costs are absorbed directly by your treatment center (hospital or physician office). The TP-HIV or the participating centres (hospitals/physician offices) can collect a reasonable user fee for the provision of samples and data. All funds are used solely for the purpose of medical research. The individual persons involved in this research will not receive any funds.

If the topics of this study are no longer relevant due to new developments, e.g. a dependable cure is developed for the HIV infection, then this study will be terminated. This study can also be terminated for other significant reasons. This decision is up to the so-called "Scientific Steering Committee" of the study.

2. What is needed and why is it needed?

Most new scientific/medical methods must initially be tested with an experiment. Such experiments often require materials, used to test the scientific problem. The stage of a disease, concomitant diseases, medications, etc. can affect the result of experiments significantly. Therefore, additional information is needed for it. To accelerate research, samples are stored today

in so-called biobanks, so that they are rapidly available for research. Overall, it is intended to observe up to 10,000 patients with an HIV infection continuously.
The biomaterials are tissue and body fluids collected from you over the course of your treatment but no longer needed during the course of your treatment. As a result, these would normally be discarded (destroyed). Examples for these are blood, urine, rinsing fluids, stool samples, or tissue samples along with special specimens such as HIV-DNA and selected blood cells. In specific cases, you may be asked for additional samples, which can be collected from you without additional stress. These include e.g. sputum, urine or swab samples. If you consent to taking blood samples, which are taken in addition to the routine blood samples (which requires no additional puncture). This blood sample will not exceed a medically acceptable volume. In general, a volume of 10-20 mL is taken (approx. 1 tablespoon). If you belong to a specific, small group of patients, who have just been diagnosed with a fresh HIV infection or who are exceptionally resistant against HIV, then you may be asked for a larger sample volume. In this event, a maximum volume of 100 mL (= 7 tablespoons) per week was set if the patient is in good health, whereby no more than 50 mL should be collected on one single day and not more than 500 mL over the course of one year. Your physician will ensure beforehand that this maximum limit is not exceeded by any potential participation in other studies. Each new blood sample collected is donated completely voluntarily. If additional samples should be collected for the study while taking a regular blood sample, then it will be pointed out to you once more that it is completely voluntarily and you can refuse donating blood without specifying any reasons for it.

3. What data are collected and how are these data processed?

The data that identify you directly remain in the treatment center (hospital/physician's office), where the samples and data were collected. They will be stored separately from the biomaterials and the medical data. They can only be accessed to conduct scientific research, to supplement them with further or missing medical data from your medical file or to contact you again, if you gave your consent to this contact (see signature page). Immediately after your samples are collected, all data, which could be used to identify you as a person (such as name, date of birth, address, etc.), are replaced by a code used to handle the samples. Personal information is not disclosed to researchers or other unauthorized persons such as the insurance company or the employer.
Data from your regular treatment is collected comprehensively and these may include all information contained in your medical file. In individual cases, your physician may ask you to complete periodically an additional questionnaire about your health condition and disease. The completion of this questionnaire is completely voluntary.

Confidentiality and Encryption of Data

For the exchange of data for the purpose of scientific research, your data are condensed to the amount absolutely necessary. They are anonymized or pseudonymized, encrypted with a secure password and handed to the office, which conducts the study, on a physical medium. Only if you have a very fresh HIV infection (within approx. the first eight weeks after infection), an additional condensed set of data will be documented in pseudonymized form in a protected online database.

Data are always anonymised, if the scientific projects permits it, e.g. if a link between your data and a sample does not have to be produced. Anonymization means that there will be no key transferred, which could be allocated to your case. Pseudonymisation means that a key is transferred, which can be used to reidentify you in your treatment center. No identifying data (no name, place of birth, date of birth) are transferred during both the pseudonymisation and the anonymization. Any further information is kept as short as possible. Please note: a slight residual risk of reidentification based on a set of data, the very good knowledge of you as a person along with your course treatment cannot be excluded 100%.

A so-called "Central Identity Management" will be established as needed to prevent that information of patients treated at several health care facilities are evaluated falsely. This means that data, which can identify you as a person, are coded at two different places (so-called double pseudonymisation), whereby any identification of you as a person by unauthorized persons can be largely excluded based on today's knowledge. The Scientific Steering Committee of the study can authorize cooperation partners to review a register of double pseudonymized samples with a descriptive clinical set of data (e.g. helper cell count, viral load, resistance pattern of the HIV infection, any concomitant diseases in connection with HIV, time lag to the infection, gender, age rounded to one full year, ethnicity, and medication at the time the sample was taken). Please note: the data managed in the register may be adjusted in the future by necessity and additional disease and treatment data may be entered into the register. We always will only include in the register the record that is absolutely necessary.

On request, the biomaterial and medical data may be transferred for medical research purposes to other universities, research institutions and companies conducting research also abroad in accordance with criteria, which were defined beforehand. In this context, the data may be linked with medical records in other databases, provided it is in accordance with the legal provisions.

Scientific articles are published in condensed form through several sets of records thereby ensuring the confidentiality of your data. If a publication is considered that carries a high risk of reidentification (e.g. detailed case report or identifiable gene segments), then you will be asked for a new written consent beforehand.

4. How is the collected biomaterial used?

The examinations on the collected biomaterials may be categorized as follows:

a. direct examinations of the biomaterial or rather the cells contained in it, their appearance, condition and biochemical properties.
b. analyses of cell components (e.g. lipids and proteins, metabolic products) including the genetic material (DNS), also genetic analyses, which theoretically could cover the entire genome
c. tests for pathogens, which can be isolated from your specimens, their appearance, condition, biochemical properties and genetic material.

All collected specimens are processed onsite in accordance with a protocol defined beforehand. They are labelled with a pseudonym and frozen. The existence of the sample is entered into a central database. Ownership rights on the samples you provided transfer to the treatment center.

5. Who is authorized to access the data and the biomaterial? What are the conditions, which must be fulfilled for it?

Initially, all data and biomaterials are only available locally at your treatment center. All interesting parties can review the Rules of Procedure and Use by accessing the homepage of the DZIF (www.dzif.de). The Rules of Procedure and Use regulate in detail the rights of use of specimens collected from you.
To be able to use biomaterials for their research, scientists must address a detailed request describing their project to a Scientific Steering Committee of the TP-HIV at the DZIF. Should the proposed research project be in agreement with the purpose of the TP-HIV and in agreement with the intent of the patients, who participate in it, then the research project is submitted to the competent ethics committee. Only after these steps will the biomaterials and data absolutely necessary handed to the applicant. The applicant may use the material and data solely for the requested purpose and must destroy or return any residuals.

6. What are the my risks, if I participate in this study?

In general, there will not be any additional invasive (stressful) measure, i.e. also not any additional venepuncture for study reasons. Therefore, there will not be any additional health risk (cp. Part 2).
There are confidentiality risks (e.g. the possibility to identify you) during every collection, storage and transmission of data from your biomaterials within the framework of research projects, particularly with regard to the information of your genetic makeup. These risks cannot be completely excluded and they increase as the volume of data able to be linked increases, particularly, if you publish genetic data on the Internet (e.g. for genealogical research purposes). We assure you that we will do anything possible under the latest state of technology to protect your privacy and to provide specimens and data only for projects, which can demonstrate a suitable data protection concept (compare Sections 3 to 6). Nevertheless, in other countries, particularly in non-European countries, the legal data protection and the enforceability of rights can differ significantly from the German provisions and possibilities.

7. What are the my benefits, if I participate in this study?

You cannot expect any direct personal advantage or benefit for your health due to the donation of your specimens and data. The results are solely intended for the purpose of research. We may contact you, if we believe that the information is of considerable significance for your health. This is the case, if an outbreak of a (potentially life-threatening) disease can be avoided or any illness previously unrecognized can be treated. However, you may have to disclose this information to other authorities (e.g. prior to the conclusion of an insurance policy). If you do not wish to be informed, then please delete the option of a new contact on the signature page.
You will not be compensated for letting us have your biomaterial and data. You will not participate in any commercial benefit achieved through this research.

8. What are my rights?

Your written consent is required for us to collect and utilize biomaterial together with the corresponding personal information for research purposes. This consent includes the possibility to

research new problems for an unspecified time without requiring from you another consent. We will inform you, if the protocol, on which this study is based, or this informed consent changes significantly.
You may request information about the personal data, we store, at any time. You have the right to have these data corrected, if needed, or deleted.
You may withdraw your consent at any time without specifying any reason for it and without any disadvantages for you. Please contact the principal investigator specified on page 1 of this document. The withdrawal does not require any special form. If you withdraw, your biomaterials are destroyed and the corresponding data are deleted. You can state in writing that you merely wish an anonymization and that any biomaterials collected up to that date may be used further. However, they can no longer be destroyed as soon as the reference of the biomaterials and remaining data about your person have been deleted. In addition, data cannot be removed from any analyses already completed. Despite the withdrawal, any later allocation of the genetic material to you personally through other sources can never be excluded.
The biobank is unable to undertake individual restrictions (e.g. exclusion from one specific research, exclusion of the transfer of the materials to third parties) for logistical reasons. If you do not fully consent to the type and duration of use as described, then your biomaterials and data are not used for the biobank.

9. Who is responsible?

The principal investigator competent at your treatment center is named on page 1 of this Patient Information. He is responsible for the execution of this study and the compliance with the study protocol. In addition, he ensures that no unauthorized person has access to the biomaterials. Moreover, he guarantees compliance with the application steps required at the TP-HIV and the competent ethics committee prior to each transfer of biomaterial.
In addition, the principal investigator is responsible for compliance with protective measures, particularly for protecting your data against any unauthorized access. He is responsible for the anonymization and deletion of your data, if you decide to withdraw from your participation in the TP-HIV at a later date (see Part 9).
While being used within the framework of this research project, specimens and data may be removed from the access area of persons competent at your health care facility. In this case, the responsibility for handling in accordance with the processes described in this document are transferred to the recipient (see Part 7).

10. Will you contact me within the framework of the translational platform HIV?

To collect data on the further course of your recovery or disease, it may become necessary for an employee of TP-HIV to contact you again at a later date to get additional information and/or biomaterial from you. If you so desire (see Informed Consent page), we can also get in touch with your family physician or with you, if during an analysis we gain medical knowledge, which is important for your treatment.

Informed consent for the participation in the translational platform HIV (TP-HIV) of the German Center for Infection Research (Deutsches Zentrum für Infektionsforschung)

Participating patient/subject: _____
(First Name, Last Name)

DOB: _____

Participant No.: _____

I consent voluntarily for my biomaterials and data to be provided in encrypted (pseudonymized) form (as described in the patient information) to the hospital/physician office, where I am treated, and to be used for medical research by the principal investigator. This may include transferring the biomaterials and data for research projects to countries, which have a lower level of data protection. I hereby transfer ownership of the biomaterials to the hospital/physician office, where I am treated.

I have read the foregoing information and I have had the opportunity to ask questions.

I consent voluntarily to genetic analyses on the material I provided.

I know that my participation is voluntary and that I can withdraw from participation at any time without stating any reasons for it and without suffering any disadvantages by it.
I consent to any later contact (if not, please check "no")

- for the purpose of further information/biomaterials, □ no
- for the purpose of obtaining consent for comparison with other databases, □ no
- for the purpose of providing me with any feedback about results that are relevant for my health □ no

You should contact the facility, where my biomaterial/data was collected or you should contact the following physician (please specify, if desired)

Name and address of the physician: _____

Privacy statement:

I consent to the treating hospital/physician office to collect from me and store my personal information

- **as described in the Information,**
- **to collect further information about my health from my medical file,**
- **and to provide the data together with my biomaterials (this means encrypts) to the TP-HIV for medical research in pseudonymized form.**

The biomaterials and data may be used for medical research for an unspecified time.

They may be transferred for medical research purposes to universities, research institutions and companies conducting research also abroad.

I have been informed that I can withdraw my consent at any time without specifying any reasons for it. If I withdraw, the remaining biomaterials and collected data are on my request destroyed or deleted or anonymised. Data from completed analyses can no longer be removed.

I have received a copy of the Patient/Subject Information and of the Informed Consent. The original remains with the treating hospital/physician office.

_____

Print Name and First Name of Participant

_____ _____

Place, Date Participant Signature

(to be completed by Participant)

I certify that I have explained the project to the above individual and that any questions about this information have been answered. The patient has provided his/her informed consent.

_____

Print Name of Physician

_____ _____

Place, Date Physician Signature