Patient Information

of the Translational Platform HIV (TP-HIV) within the framework of the

German Center for Infection Research

| Project Management: | Substitutes: |
|---|---|
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| Attending clinic / medical practice: | |

Dear Patient,

We would like to ask you to participate in the research project described below to be conducted within the framework of the German Center for Infection Research (Deutsches Zentrum für Infektionsforschung (DZIF)).

In spite of the progress made in recent years, HIV cannot be healed to this day. There are still open questions regarding possible long-term effects of the disease or its treatment respectively. Your attending clinic / doctor's practice is participating in the cohort study titled Translational Platform HIV (TP-HIV) of DZIF. Within the TP-HIV, observations are based on the collection of data and biomaterials. The information gained from this has become an important instrument for medical research. That is why we are asking all patients, male and female, whether they would be prepared and willing to provide us with certain biomaterials or data for research purposes. Your participation is voluntary. There will be no drawbacks for you if you should chose not to participate or to discontinue your participation at a later time. This study was presented to the competent ethics committee and was assessed positively by the latter.

Please do not hesitate to address any issues you feel uncertain about. You may contact your investigator or project manager as referenced on page 1 at any time. For more background information regarding TP-HIV please refer to the flyer titled *"TP-HIV of the DZIF"*.

## 1. What will the biomaterials and data be used for?

TP-HIV is an open-source collection of biomaterials and data that is intended to assist in finding answers to scientific issues quickly and successfully in future. Prior to any such use, scientific projects will be reviewed by the steering committee for the study and, for biomaterials, also by the competent ethics committee. It is a basic requirement for any use of your data or biomaterials that the scientific issue concerns people living with HIV and it must potentially benefit these people. We follow new and resolved

scientific issues closely, and will only use your data or biomaterial if, in our opinion, scientific use is likely.

## 2. What is biomaterial and why is it required?

The biomaterial collected comprises tissue and body fluid samples that were taken during your treatment, but that are no longer required for examinations within the scope of your treatment and that will otherwise be destroyed. Examples of this are blood, urine, irrigation fluids, stool samples or tissue as well as special preparations (such as HIV DNA or selected blood cells). In certain instances, you may be asked to provide additional samples or specimens if these can be obtained without any additional burden on your part. If additional blood samples are to be taken during a regular withdrawal of blood samples, you will be asked again beforehand, and you may refuse to provide such samples without giving reasons. There will be no additional puncture, and the blood sample volume that is justifiable from a medical point of view (10 to 20 ml, approximately a tablespoonful) will not be exceeded. If you are a member of a rare group of patients such as those with a recent HIV infection we may ask you to provide a somewhat larger sample volume. In such cases, a maximum volume, assuming good health, has been set at max. 100 ml (equals seven (7) tablespoonfuls) per week, with no more than 50 ml being taken on any one day and not more than 500 ml in any one year. Prior to this, your doctor will make sure that this upper limit will not be exceeded by your possible participation in any other studies.

## 3. What kind of data will be collected and how is it processed?

Within the TP-HIV, we will collect your medical findings, treatments and personal data. In individual cases, you may be requested to complete an additional questionnaire regarding your state of health and illnesses. This information will be saved in a medical database. Data privacy regulations will be duly observed and complied with in this process as described below.

### *Data privacy and data coding*

All data is subject to the statutory provisions of the German Federal Data Protection Act (BDSG), the European General Data Protection Regulation (GDPR) and doctor-patient confidentiality. Your data will be reduced to the volume absolutely required for the purpose of scientific investigation, and will only be saved in a pseudonymized format. The data and biomaterials will be protected against unauthorized access. The pseudonym can only be assigned to you by the attending investigator. Any such assignment will only take place under the conditions prescribed by law. Should, in spite of the precautions taken, a violation of the protection of personal data occur that would likely result in a high risk to your personal rights and freedoms, you will be advised accordingly by the project management without any undue delay. To prevent information from patients who are being treated at or by several health care facilities, from being incorrectly evaluated, it may be appropriate to establish what is called a “central identity management” system. Here, any data that would identify your person will be coded at two different points (so-called double pseudonymization) which, to the best of our knowledge, prevents the unauthorized identification of your person. The scientific steering committee for the study may grant cooperation partners the right to inspect an index of double pseudonymized samples with a descriptive clinical records (such as the number of helper cells, viral load, resistance pattern of the HIV infection, secondary illnesses related to HIV, time that has elapsed since the infection, sex, age rounded to the nearest year, the country of origin and medication at the time the specimen was collected). Please note that the data maintained in the index may have to be adapted or adjusted in the future or that additional medical records or treatment data may be included in the index. We will only ever include those records in the index that are absolutely necessary.

## 4. How will the collected biomaterial be used?

The examinations have not been finally determined at this juncture and will be based on what is technically feasible. As a matter of principle, all of the material should be appropriate for use for scientific purposes, which includes all tissue, cells, cellular constituents, body fluids or excretions. The investigations may also include genetic investigations up to and including the complete decoding of the genome on your cells and all organisms contained in the collected specimens. Within the scope of these investigations, pathological findings (also known as chance finds) may be found such as the presence of a hereditary disease of which you were unaware. Information regarding your genetic makeup may also be of significance to your family members, to family planning or birth control or may even have insurance law implications (e.g., on the terms of life insurances). You should discuss chance finds with your attending doctor and / or with a human geneticist. The availability of your specimens will be entered into a centralized database. The property rights to the specimens you have provided will be transferred to the attending center.

## 5. Who will be authorized to access the data or biomaterial? What requirements must be satisfied to do this?

For the time being, all data and biomaterials will be available locally at your attending center. The rules of procedure and use can be viewed on the TP-HIV homepage (www.tp-hiv.de) and regulate the rights of use to the samples and data obtained from you. In addition, duly authorized agents of the competent ethics committee may request to inspect your original personal data.

Within the scope of future research projects, specimens or products isolated from these may be made available to scientists or institutions at home or abroad for defined investigations. To be able to use biomaterials, a detailed application must be submitted to the TP-HIV scientific steering committee at the DZIF and to the competent ethics committee. Only following approval of the application will the biomaterials or data absolutely required for the research project be surrendered to the applicant. The specific whereabouts of the specimens will be documented so that you may obtain information regarding the recipients of the specimens at any time. Should any data be published, this will happen without any direct reference to your person.

Different, and often less strict, data privacy legislation may be in place in non-EU countries. If the research question allows it, we will reduce the data volume and anonymize your data completely. We still ask for your consent to make pseudonymous data available for promising scientific projects where this should be required. We will exclusively cooperate with professional partners who have comprehensive experience in the management and evaluation of patient data. We will procure assurances from our partners that the data will be handled with the utmost confidentiality and in accordance with the principles of the EU GDPR. For our part, we undertake to represent your rights to the fullest extent possible towards our partners and to disclose any violations that come to our attention. However, in cases of doubt we will not be in a position to legally enforce this, and we point out that this constitutes a transmission according to Section 49 (1) a) EU GDPR. For you, this means that to enforce all of your rights under EU GDPR, and especially your rights to obtain access to your data, or to obtain the correction or erasure of your data, you may have to rely on legislation existing in the third country and the good will of our partners, but you may have no or limited options of legal recourse. Also, we know from the US and other countries that government agencies or secret services may access certain data. The local project management (as specified on page 1) is responsible for data processing.

## 6. What are the risks I face if I participate?

There are no study related additional interventions or medication. There is, therefore, no additional health risk (cf. Section 1).

## 7. What benefit will I have from my participation?

Your participation in this study will not entail any immediate benefits as such. Through your participation, however, you will be contributing to the gaining of new knowledge in the field of HIV research. Also, your participation in this study may facilitate more selective and specific therapy decisions in future. You will not receive any consideration for your participation in this study.

## 8. What rights do I have?

The processing of personal data is only legitimate subject to your consent. You are entitled to revoke your consent to the processing of personal data at any time. In spite of your revocation, however, it cannot be ruled out with absolute certainty that your genetic material will be allocated to your person via other sources at a later time. In the event of revocation, your data must be deleted upon your request. Until said revocation, the processing of your data will be legitimate. You may issue a request for information regarding your saved personal data (including the free transfer of a copy in hardcopy form or digital format). You are also entitled to request the correction of this data. If you want to exercise any of these rights, it is preferable that you contact project management or the data protection officer at your test center. In addition, you will be entitled to lodge a complaint with the competent regulatory authority if you consider that the processing of the relevant personal data occurs in violation of the GDPR. We will advise you should changes be made to the study that are relevant to you.

## 9. Who will bear responsibility?

The competent project management at the attending center will be responsible for this study and for compliance with the study protocol, and will ensure that no unauthorized third parties access the data or biomaterials. In addition, the local project management will ensure compliance with the required application procedure at TP-HIV and the competent ethics committee prior to any disclosure or the dissemination of any biomaterials. It will also be responsible for pseudonymization / anonymization and deletion (see Section 3). Both specimens and data may be removed from the access area of the persons responsible at your health care facility when used within the scope of a research project. In such an instance, the responsibility for handling according to the present document will be transferred to the recipient (see Section 5).

## 10. Will I be contacted by you in the context of the TP-HIV?

To collect data for the further course and progress of your recovery or illness, it may be necessary for employees at TP-HIV to contact you again at a later date to obtain supplementary information and / or biomaterials or if we should gain medical information that would be critical to your treatment within the framework and in the course of investigation.

By signing this document I declare that I have read the *Patient Information of the TP-HIV within the framework of the DZIF* I have received a copy of this Patient Information.

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Full name of the participant (please print)

_____ _____

Place and date **Participant's signature**

# Informed Consent

I have received, read and understood the written explanations (Patient Information, annex to the Informed Consent) relating to the TP-HIV. All questions that arose when I read these documents were answered in a direct conversation. I have been advised that I may revoke my consent to participate in this study, given today, in full and without giving reasons at any time and that I will suffer no disadvantages due to such revocation. Furthermore, I may request at any time that my blood samples or tissue specimens or any fractions separated therefrom be destroyed. By my consent to participating in this study I waive any claims I may have under any copyright or patent law. All intellectual property rights in the form of the data or results obtained will remain with the scientific management of this project. The blood sample and the fraction of the tissue specimen that may be made available to the study will become the property of the attending center.

Personal data will be collected from you within the scope of this study. Any and all persons who will be able to access said personal data will be obligated to comply with applicable data privacy requirements. Your name will not be publicized at any time. Your data will be encoded after collection. Your sample materials and specimens, will also be encoded after collection. The data will be handled in accordance with the above-referenced principles and standards.

| I hereby consent / do not consent to the following items: | |
|---|---|
| I consent to my **biomaterials** that are no longer required for medical purposes being transferred – without compensation – to the ownership of the attending clinic / medical practice and to their being used for research projects that may produce results relevant to people living with an HIV infection. This may also include disclosure for research projects abroad with potentially inferior data protection levels. I am aware that, as a result, I may not be able to enforce my rights under the EU GDPR; this especially includes rights regarding access to, and the correction or erasure of said data. I have duly read and understood the detailed comments provided in Section 5. I am aware that new investigation procedures and / or genetic analyses up to and including the determination of the complete genetic material (DNA) may be conducted on my biomaterial. | ☐ yes ☐ no |
| I consent to my **data** being transferred to the property of my attending clinic / medical practice in coded (pseudonymized) form and being used by the project manager for medical research purposes. This may also include disclosure for research projects abroad with potentially inferior data protection levels. I am aware that, as a result, I may not be able to enforce my rights under the EU GDPR; this especially includes rights regarding access to, and the correction or erasure of said data. I have duly read and understood the detailed comments provided in Section 5. | ☐ yes ☐ no |
| I explicitly consent to my pseudonymous data being passed on to third party countries in accordance with Section 49 (1) a) for scientific purposes without the submittal of an adequacy decision and without legally enforceable guarantees. I am aware that, as a result, I may not be able to enforce my rights under the EU GDPR; this especially includes rights regarding access to, and the correction or erasure of said data. I have duly read and understood the detailed comments provided in Section 5. | ☐ yes ☐ no |
| I consent to the principal investigator(s) or a duly authorized study employee contacting me in future, following consultation with the data protection officer or the competent ethics committee, to propose possible follow-up examinations. | ☐ yes ☐ no |
| Pathological finds (also known as chance finds) may be discovered within the scope of scientific analyses and / or genetic testing of which I have not been aware and that may be critical to my further treatment or my health (such as the presence of a hereditary disease). I hereby consent to being advised of such chance finds by my attending doctor in any event. | ☐ yes ☐ no |
| I also make my data available for commercial research projects. | ☐ yes ☐ no |

By signing this document, I declare that all of the above applies and that I am willing to participate in the TP-HIV study under the above conditions. I have received a copy of this Informed Consent and of the associated Patient Information.

_____ _____

Place and date **Participant's signature**

I have conducted the informed consent discussion and I have answered all questions I have been asked in the process. The Patient has given his or her consent.

_____ _____

Place and date **Doctor's signature**