

Patient Identification Number (PID) \_\_\_\_\_



## Patient Information

Dear Patient,

You are in medical care in our institution to treat your HIV infection. HIV infection can be treated much better today than was possible a few years ago, but many questions and problems remain. Just a few examples: What drugs are best for initiating a therapy for the HIV virus? How can side effects be avoided or alleviated? What influence does the immune system have on the course of the HIV infection?

We would like to ask you to participate in the *Competence Network* on HIV/AIDS to help us in our research on open questions on the HIV infection. By doing this, you would give us access to the data on the course of your infection and on your treatment.

We would like you to take this patient information home and to read it carefully. If there is anything that you do not understand or something that you would like to know more about, please ask your physician. You can also obtain further information from one of the contact persons listed at the end of this text. You will receive a copy of your signed declaration of consent. The physician treating you will retain the original of your declaration.

### What is the *Competence Network* on HIV/AIDS?

The *Competence Network* on HIV/AIDS is supported by the German Federal Ministry for Education and Research. The *Competence Network* bundles the work of physicians concentrating on HIV in private practice and in hospitals in Germany as well as researchers studying the HIV infection. It is directed by a committee consisting of physicians, researchers, representatives of the German AIDS-Hilfe and patients' representatives. Its chairmen and speaker, Professor N. H. Brockmeyer (Ruhr-University Bochum) is responsible for the Network.

To document the course and treatment of the HIV infection, the *Competence Network* collects patient data (cohort data) as well as certain specimens, in particular blood specimens. The responsible person regarding data management is the speaker of the network. Supervised and by order of the *Competence Network*, the data are stored and analysed at the Centre for Clinical studies (CCS) in Cologne and other qualified bodies and researchers. Blood specimens are kept by all participating practices and hospitals in the *Competence Network*. Other material specimens such as specimens from your intestinal mucosa are only collected at certain centres. A separate declaration of consent is presented for examinations done on tissue specimens. Whenever a researcher participating in the *Competence Network* would like to study a medical problem with material specimens, the *Competence Network* can give him or her access to the specimens. Your physician would be pleased to provide you with an explanation of the activities of the *Competence Network*. Data and biological samples could be distributed also to international collaborations located outside Germany.

If industrial (commercial) partners are involved in a project, data and biological samples will be distributed to them only, if these partners will contribute to the *Competence Network* financially. This is required due to the timely limited support of the *Competence Network* by the Federal Ministry for Education and research. Information on sponsors, and kind and extent of their contributions as well as the use of these are

published regularly on the Website of the *Competence Network* ([www.kompetenznetz-hiv.de](http://www.kompetenznetz-hiv.de)) and in its newsletters.

Another point in this regard: The results gained by the *Competence Network* can result in patents registered either by the *Competence Network* or participating researchers. It may be that the researchers gain the knowledge that makes this possible by using your data or your biological material. As long as you are not yourself an intellectual originator of this knowledge, you cannot be given a share in the patents.

Your physician will be pleased to provide you with an explanation of the activities of the *Competence Network*. In this explanation, we describe what a cohort study is and list questions that the *Competence Network* can study.

### **What can you expect from participating in the *Competence Network*?**

It will involve no additional demands on you or visits to a physician. Your treatment will continue normally. The only difference is that the physician treating you will forward your medical data to a central database. You may be requested to give additional blood samples. On this point, please read the section “additional blood samples” further below.

We would like to emphasise that the *Competence Network* on HIV/AIDS will **not** influence your and your physician’s treatment decisions; in particular, there will be no influence on you with a view to answering a certain research question. Therapeutic decisions and your HIV treatment do **not** depend on your participation in the *Competence Network*. **Naturally, you are completely free to participate in other research projects at the same time (for example, medication studies).**

At this point we would like to raise a question in connection with the research results obtained in the *Competence Network*: How much would you like to know? As a matter of principle, you have the right to receive all information about examinations of your blood samples or other materials. However, if you have a genetic factor that could accelerate the infection, it may be detrimental to your health to learn of this fact. Simply because you then worry that in your case the disease will run its course more rapidly than in other patients, it will do precisely that. If you were not made aware of the fact that your prognosis is less favourable, it may not turn out this way. For it is almost never the case that such prognoses come about for all people.

In other cases, a result can be irrelevant for you. Looking at the example of initiation of therapy, this could be the case if you are already receiving antiretroviral therapy. Possibly, insurance companies will ask for results of genetic analyses before contracting to estimate the insurance risk (e.g. regarding health insurance or occupational invalidity). If you are aware of genetically caused risks, you may be obliged to state this before contracting.

### **Which benefits do you have as a HIV patient by participating in the *Competence Network* on HIV/AIDS?**

First of all: if you participate in the *Competence Network*, it does not mean that you will automatically be selected for a clinical study on, say, new, experimental drugs.

However, cohorts can raise important questions for patients, physicians and researchers – even though the cohorts cannot answer the questions. To this aim, smaller, specific studies are necessary. (You can read more detailed explanations in the additional information that your physician can provide you with.)

Thus, as an HIV patient you have no direct benefit from participating in the *Competence Network*. But in the medium and long term, your participation will help answer important open questions that HIV therapy has been faced with for many years. This will improve the quality of treatment, the survival time and the

quality of life of people with HIV/AIDS. Moreover, your participation will naturally help people with HIV/AIDS who are not yet being treated.

## Voluntary Participation

**Participation in the *Competence Network* is voluntary. As a matter of course, you can withdraw your consent at any time without having to state reasons.**

Non-participation or revocation of your consent will have no negative consequences for you and your HIV treatment. In the next section, you can read what will happen to the data on you that we have already stored in case you withdraw.

At any time, you have the right to receive information on data stored, to have incorrect data corrected or to have data deleted. If you agree to participate in a further in-depth study as part of the *Competence Network*, you will be requested to give a separate declaration of consent for this project.

If you wish to withdraw your consent to participate in the *Competence Network* on HIV/AIDS, please contact the physician treating you. In exceptional cases, you may contact the cohort manager to withdraw your consent.

## What data are stored? How are they handled?

Within the *Competence Network*, a distinction is made between **identifying** data and **medical** data. The **identifying** data comprise your family name, given names and your address. Only the physician treating you is knowing these data. In some cases, a monitor can have access to the identifying data (see below) to verify your **medical** data. Additionally, there are sociodemographic data as apprenticeship, origin and income.

Before your physician forwards the data, the **identifying data** will be removed from the dataset. Your physician encodes the dataset using a number, which pseudonymises the data in pseudonym combined with your clear name. You will receive a print version of your declaration of consent and your pseudonym. Your physician is not allowed to and will not submit your identity to the *Competence Network*. **The *Competence Network* does only know your pseudonym and your treating physician, but not your identity.** If you change your treating physician, please tell your new physician that you already participate in the *Competence Network*. The Network will merge data collected by your old and your new physician. Doing that, it is guaranteed that we will not store your data twice.

We store the **medical** data with the pseudonym in a central data base and analyse them anonymously. This way, we make it impossible for unauthorised persons to link **identifying** data with the **medical** data. **This protection is also given if your data or samples are analysed abroad.** The *Competence Network* will proof for every single study individually, which data and/or samples are distributed for analyses and if there are special risks as to data protection.

In case of a publication of results, it will not be possible to identify who participated in the *Competence Network*. It will not be possible to establish any relationship to your specific person.

The **medical** data contain information on your disease. It is also intended to collect more specialised data, for example on the effect of the HIV infection on the gastrointestinal tract or the central nervous system. In most cases this will involve medical details that your physician is aware of anyway. Furthermore, some sociological data such as your origin and your occupation will be collected. If you decide to participate in the *Competence Network*, your physician will forward these data to the *Competence Network* as soon as it requests. If you wish, you can view the complete data record on the website of the *Competence Network*. It may also happen that, for example, we request data describing your living situation. In such a case, your

physician would have to present you with a questionnaire. You can then decide from case to case whether you wish to complete it.

The *Competence Network* cooperates with foreign partners in case of specific research questions. Idea is to have a very large data basis, e.g. by combining data of several cohorts. By doing that, researches will be enabled to analyse rare phenomena, that can not be analysed by using data of just one cohort.

Data and biological samples (blood and DNA-) samples are analysed in the same pseudonymised way in foreign laboratories/research centres as in Germany, depending on the study. **Your identity is protected in the same way as in Germany as to submitting and analysing data and biological samples.**

If you revoke your consent to participate in the *Competence Network*, your **medical** data will normally be made anonymous. To do this, the **identifying** data in the custody of the data trustee, your patient identification number and your declaration of consent will all be erased so that you can no longer be identified. At the same time, the pseudonym will be removed from your blood samples in storage. At your explicit request, all medical data about you and specimens from you in the possession of the *Competence Network* shall also be destroyed.

Your physician will be pleased to provide you with a list of the data collected.

### **Planned Modifications (not yet implemented)**

In case you will change your treating physician the *Competence Network* **plans** to facilitate combination of medical data of your old and new physician (especially if the cohort contains several thousand of patients), by storing the lists of pseudonyms centrally. For this purpose, the *Competence Network* will mandate a lawyer or solicitor as a data trustee. Then, your pseudonym will be generated and administered by this data trustee and to by your physician any longer. Doing that, it will be guaranteed that every treating institution you are visiting is using the same pseudonym. Your treating physician will be able to give you information on the data trustee as soon as he will be assigned.

The data trustee will store your **identifying** data and your pseudonym in a secure place. So, your **identifying** data will be stored separated from your **medical** data. This means that the two databases will be located in two different places. There will be nobody who has access to both databases.

If we will inform you about scientific results or if we would like to inform you about the possibility to take part in a clinical study, this will be only by the data trustee or by your treating physician (s below). Only these persons and yourself know, which pseudonym is related to you.

If you withdraw your consent to participate in the *Competence Network*, your identifying data and your pseudonym will be deleted by the data trustee.

### **When and by whom will your *identifying* data and your *medical* data be linked (who knows that you are participating in the *Competence Network*)?**

There are only three cases in which your **medical** data and your **identifying** data can be brought together.

1. Researchers would like to perform an in-depth study on a medical question resulting from the analysis of data from the *Competence Network*. After approval by the committee on data protection in the *Competence Network* on HIV/AIDS, the data trustee will then ask the physician treating you to ask you if you would like to participate in the study.
2. The analysis of the data has led to knowledge that we would like to inform you about, for example if in the analysis of cohort data we have noticed a particular side effect of one of the drugs you are receiving. Here, too, the mediators are the data trustee and the physician treating you.

3. To verify the data, a *Competence Network* monitor (a data inspector who is not involved in the scientific analysis of the data) may view your patient record. To this end, the monitor will contact your treating physician, as long as no data trustee is assigned. Later, the monitor will get your identifying data by the data trustee.

A few words on point 3: When the data are entered and transferred, errors cannot always be avoided. However, data errors can reduce the quality of the scientific studies. To avoid this, a *Competence Network* monitor (data inspector) is supposed to compare the data entered with the data in your physician's record. For this reason, in addition to the physician treating you the *Competence Network* monitor can also access your **medical** data to check them. For a brief period, the monitor may also use your *identifying* data to compare the *Competence Network's* data with the data that your physician has stored about you. The monitor will check about 10 percent of the data stored by the *Competence Network* in this way. Whose data will be checked is decided by the monitor by drawing lots. The monitor is professionally qualified as a medical documentation specialist or physician or has another comparable qualification, and is prepared for the task by means of specific training and further education. The monitor is subject to the obligation to maintain confidentiality. The monitor only has access to the data list prepared for monitoring, and has no further access to the medical data of the *Competence Network*.

Two last possibilities of deciphering should be mentioned here, although they are extremely improbable. By means of a court order the physician's or the data trustee's immunity from seizure can be annulled. Moreover, the blood samples can be identified by means of a comparison of DNA specimens since they contain a genetic code specific to the person.

**To underline:** within the scope of a regular use of the database of the *Competence Network* or of analyses of data and biological samples, **you can not be identified!**

### **Additional blood samples**

Per year, we need about 20 ml of blood in addition to normal checkups; every 6 months, 10 ml of your blood will be taken. The physician treating you will freeze and store the blood. The *Competence Network* can use these samples to work on medical questions that turn up later on the basis of new knowledge gained by HIV research.

Finally, we would like to take one blood sample of 9 ml as a DNA specimen at your entry into the *Competence Network* and 3 years after that, in order to gather further medical data. Assigning a pseudonym to the data makes it possible to re-identify the patients so that if you request it you can receive genetic counselling. The mediators are the data trustee and the physician treating you. With this sample, we would like to study the question as to what hereditary factors (genes) of a patient determine how he or she responds to therapy and what side effects occur. Furthermore, we would like to detect the hereditary factors (genes) now largely unknown that determine how well the body's immune system can attack the HI virus. We hope that it will be easier then to find the best possible treatment for every patient. This applies both to the kind of treatment and to the time at which it is initiated.

Your physician will take the blood when your blood sample is taken anyway for a checkup. A separate blood sample appointment is not necessary.

### **For how long does the *Competence Network* on HIV/AIDS store data and material?**

The *medical* data are made anonymous as soon as the research project is ended. If, however, you do not receive treatment from a physician participating in the *Competence Network* for a period of six years, we shall then make the *medical* data anonymous. Your *identifying* data will then be erased so that the *medical* data can no longer be assigned to a specific person.

The blood samples in storage that you have given will be destroyed at the latest 6 years after the last treatment in the *Competence Network* on HIV/AIDS.

### **Do you have any further questions?**

If you have any questions about the *Competence Network* on HIV/AIDS, please consult the physician treating you or contact the scientific coordinator of the *Competence Network* or the coordinator of the German AIDS-Hilfe directly:

Cohort Manager of the Competence Network for HIV/AIDS  
Clinic for Dermatology and Allergology of the Ruhr-University Bochum  
Gudrunstrasse 56, D-44791 Bochum, Germany  
Tel.: (0234) 509-3501, Fax: (0234) 509-3475

Coordinator of the Competence Network within the German AIDS-Hilfe  
Dieffenbachstr. 33, 10967 Berlin  
Tel.: (030) 69008788

You can also find information on the *Competence Network* on HIV/AIDS in the Internet at  
[www.kompetenznetz-hiv.de](http://www.kompetenznetz-hiv.de)

**We extend our sincere thanks for your participation!**

**Further remarks and wishes**

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Patient Identification Number (PID) \_\_\_\_\_



## Declaration of Consent

I \_\_\_\_\_

born on \_\_\_\_\_

have been informed in detail in writing and orally by  
the physician treating me, Mrs./Mr. \_\_\_\_\_

about the nature, significance and goals of the *Competence Network* on HIV/AIDS.

I have received the written patient information on the *Competence Network* on HIV/AIDS. I have been given a copy of the patient information and the patient's declaration of consent. I have read and understood both. I have been informed of my rights to data protection. I have had sufficient opportunity to ask the physician treating me questions and enough time for my decision.

I hereby declare that I will participate in the *Competence Network* on HIV/AIDS. I have been informed that my participation is voluntary and that I have the right to end it at any time. I do not need to state reasons for this. I shall not be subject to any disadvantages because of this.

**I will participate in the *Competence Network* on HIV/AIDS and give my consent to the electronic processing of my data as described in the patient information.** The medical data shall be stored with a pseudonym in the central data base of the *Competence Network* and, like the biological samples, analysed in Germany and, if applicable, abroad, without any regard to my identity. In particular, I give my consent that my treating physician (resp. the data trustee, in the future) may decipher my pseudonym so that a *Competence Network* monitor can check my medical data. To this end, the monitor may view my personal patient documentation held by the physician treating me.

**yes**       **no**

I consent to an additional sample of about 20 ml of blood per year which shall be stored for future research. I have been informed that these samples will make it possible to work on questions that come up at a later time on the basis of new knowledge gained by HIV research.

**yes**       **no**

I consent to two additional samples of 9 ml of blood as a DNA specimen (once at study entry, once 3 years afterwards). I have been informed that it shall be used exclusively to study genetic factors that play a role in HIV infection.

**yes**       **no**

I consent to being re-contacted later by the *Competence Network* via the physician treating me, for example if I seem suitable as a participant in a study within the framework of the *Competence Network* on HIV/AIDS.

**yes**       **no**

Information about findings:

- On principle, I would like to be informed about all knowledge that the *Competence Network* yields about my HIV infection.
- I would like to be informed about the results obtained by the *Competence Network* about my HIV infection only if my physician considers it to be medically useful and reasonable.
- I do not wish to be informed about the results obtained by the *Competence Network* about my HIV infection at all.

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Place, date

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Patient's signature

The patient was informed by me of the nature, significance and goals of the *Competence Network* on HIV/AIDS and advised that he or she can revoke his or her consent at any time without stating reasons.

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Place, date

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Physician's signature