

Dear Sir/Madam,

You regularly attend the HIV outpatient clinic for check-ups relating to your HIV infection. To give you the best possible treatment, your HIV treating physician and/or HIV nursing consultant collect your personal and medical data in your medical file. With your explicit consent, your data may also be used by stichting hiv monitoring (SHM) for scientific research. This letter contains more information about this research and explains how you can give consent.

About stichting hiv monitoring (SHM)

In 2001, SHM was appointed by the Dutch Ministry of Health, Welfare and Sports (VWS) to be the organisation responsible for carrying out the registration and monitoring of people living with HIV in the Netherlands. To fulfil its monitoring tasks, SHM collects data from all those people who attend one of the recognised HIV treatment centres in the Netherlands for check-ups. These data provide a unique insight into the course of the infection and the effect of its treatment, and for this reason are of great importance to the monitoring of HIV in the Netherlands.

SHM works closely with a number of organisations (including the National Institute for Public Health and the Environment (RIVM), HIV treatment centres, and national and international research institutions) to systematically collect, analyse and report on data on HIV and HIV treatment. SHM's activities serve the interests of public health, support scientific research and are not of a commercial nature. SHM carries out its work with a grant from the VWS. SHM has an organizational structure with a supervisory board. The supervisory board comprises representatives of the HIV patients' association, the Dutch Association of HIV-treating Physicians, the Netherlands Federation of University Medical Centres, the Dutch Hospitals Association, the Dutch Health Insurers (ZN), Amsterdam UMC, and the Netherlands Association of Community Health Services (GGD GHOR).

This letter contains information about:

- why and how SHM collects your data at an HIV treatment centre and checks them for accuracy;
- the sort of data that are collected for HIV monitoring and how your privacy is safeguarded;
- where and how your data are stored;
- who your data will be exchanged with;
- how you can withdraw your consent to the collection of your data;
- your rights in relation to your data;
- where to find more information and where to ask questions.

You can also view the short information film on the SHM website or download the patient brochure: www.hiv-monitoring.nl

Why your data are collected

SHM will use your data for the purpose of national HIV monitoring and for scientific research. SHM works in scientific collaboration with researchers in the Netherlands, Europe and elsewhere in the world.

The outcomes of this research will contribute to an improvement in HIV care in the Netherlands by increasing our knowledge about HIV and its prevention and treatment. In this way, SHM will gain more insight into which treatments are effective, which treatment side effects occur most often, how the number of HIV diagnoses in the Netherlands changes each year, what other diseases occur as people grow older, e.g., cardiovascular disease, and other information that may be important in the treatment and prevention of HIV.

More information about our collaborative partnerships and research can be found on www.hiv-monitoring.nl

When, where and what sort of data are collected from you and how SHM safeguards your privacy

When you enter care at an HIV treatment centre, an HIV treating physician or HIV nursing consultant will ask you if you wish to take part in the national HIV monitoring programme. If you give your permission, the HIV treating physician or HIV nursing consultant will note this down in your medical file and SHM will subsequently register this in their national database.

Collection of your data and quality checks will take place within the HIV treatment centre. Once you have given your explicit consent, SHM's data collector will collect the relevant data from your medical file. SHM's data quality officer carries out quality controls on these data by comparing the data in your medical file with the data entered into SHM's national database.

You can withdraw your consent at any time. You will find more information about this in the "Privacy rights" section of this letter.

If you give your consent, the following data, for registration at SHM, will be collected:

- date of birth;
- initials (max. 2 letters);
- gender;
- nationality and country of birth; the 4 numbers of your postcode (not letters);
- data from an earlier registration with SHM, if you have previously attended another HIV treatment centre;
- hospital registration number.

Your registration data will be saved under a unique code number. Using this code number, the data collector will periodically collect those medical data that are relevant to national HIV monitoring. These are data relating to your medical history, your HIV diagnosis, your treatment, the progress or course of your infection, and any other directly or indirectly related infections and diseases. Each time you visit the outpatient clinic, these data are recorded in your medical file by

the HIV treating physician or HIV nursing consultant. Your medical data will be separately stored from your registration data.

Your consent also means that relevant data can be collected from other HIV treatment centres where you have been treated for your HIV infection. You are also giving consent to the use of relevant provisions obtained from blood samples taken during the course of your treatment, including medical data from leftover blood samples material stored in the laboratory. These medical data can be used for scientific research during the national HIV monitoring programme.

If you are pregnant, then the information recorded in your file on your pregnancy, the birth, and some birth data about your baby that are relevant to HIV monitoring will also be collected. The birth data are: duration of your pregnancy, gender of your baby, birth weight, breast feeding, measures taken to prevent your baby from acquiring an HIV infection, and any complications surrounding the birth, including death, birth abnormalities, and the HIV status of your baby.

All your data will be stored under a unique code number. Only the data collector, the data quality officer, the HIV treating physician and HIV nursing consultant can trace you as a person from this code number. None of the other members of staff or researchers at either SHM or the treatment centre are able to do this.

An extensive list of all the data that are collected can be found on the SHM website: www.hiv-monitoring.nl.

Use data of other registrations

In the interest of HIV monitoring and surveillance in the Netherlands your, not directly traceable, data can be linked with other registrations. If it is necessary to link the data within the treatment center, SHM always uses a Trusted Third Party (TTP) that, as an independent party, ensures that the data exchange complies with data protection laws and regulations.

Information about current links to other registrations can be found on our website: www.hiv-monitoring.nl.

If you do not give consent, then only your basic data will be registered so that the correct number of HIV infections in the Netherlands can be reported to Cib-RIVM.

These data are:

- year of birth;
- gender;
- born in the Netherlands: yes/no. These data are anonymous and cannot be traced to you as a person in any way at all.

How your data are stored

Your data are stored in SHM's secure national database. Those persons who have access to this database are all bound to a professional (medical) duty of

confidentiality. SHM applies very strict access and safeguarding measures. The exchange of data is always coded so your privacy is optimally protected.

Who your data will be exchanged with

SHM only provides research institutions with data **that cannot be directly traced back to you as a person**. Data are only shared after a research proposal has been submitted to SHM, checked and approved, and if the research institution complies with **strict legal and ethical conditions**.

Only those data that are necessary for research are exchanged. Clear agreements are made with the relevant institutions about the use of these non-directly traceable data. For example, the data may only be used for approved research, they may not be shared with other parties and after the research has been completed they must be destroyed.

The data that are included in the publication of study results are anonymous and cannot be traced back to you as a person. In this way, SHM complies with privacy legislation and the laws and regulations on medical research.

SHM does not provide data to commercial parties such as insurers or pharmaceutical companies.

How long will your data be stored?

With your consent, your data will be stored for as long as the national HIV monitoring programme in the Netherlands is ongoing.

The medical data obtained from the material left over from your samples can be used for medical research for the duration of HIV monitoring in the Netherlands. No legal retention periods apply to the storage of leftover material for scientific research; it will be kept for as long as it can contribute to scientific research.

Your privacy rights

Under the privacy law General Data Protection Regulation (GDPR) you have a number of privacy rights. These rights are listed below, together with a description of each right, explaining exactly what it means for you if you exercise it.

- **Right to be forgotten/erasure:** You have the right to have your data removed by withdrawing the consent that you have previously given. *After your consent has been withdrawn, SHM will no longer collect data from your medical file or from the leftover material stored at the hospital and your personal data will be anonymised. Data collected in the national SHM database up to that point will no longer be used for new studies.*
- **Right to object:** You have the right to object if you feel that your data are being used for something other than the original purpose. *This right applies if you feel that you have never given permission for scientific research by SHM. If you believe that you have not given consent, SHM will stop collecting data from your medical file and from the leftover material stored at the*

hospital and your personal data will be anonymised. Data collected in the national SHM database up to that point will no longer be used for new studies.

- Right to rectification and addition: If your personal data are incorrect or incomplete, you have the right to have them corrected. *Changes and additions made to your medical file by an HIV treating physician or HIV nursing consultant will be processed by the data collector and included in the national SHM database.*
- Right to restrict processing: You have the right to temporarily stop the processing of your personal data. *By temporarily withdrawing your consent and then giving it again at a later stage, you can temporarily stop the processing of your data in the national SHM database.*
- Right of access: You have the right to access your personal and medical data. *SHM cannot give you direct access to the national SHM database, as your data are collected and stored in encrypted form. However, you can view the data that have been recorded in your medical file by an HIV treating physician or HIV nursing consultant.*
- Right to data portability: You have the right to transfer your data to another party. *SHM cannot transfer your data as your data are collected and stored in encrypted form in the national SHM database. However, you can transfer the data from your medical file.*

How to exercise your rights

SHM stores your data in the national SHM database in encrypted form, which means that your data cannot be traced directly. Therefore, you cannot withdraw your consent or make an objection directly to SHM. However, you can tell the HIV treating physician or HIV nursing consultant that you are withdrawing your consent, making an objection, or exercising another right.

When you exercise your rights, the HIV treating physician or HIV nursing consultant is legally obliged to establish your identity, and can therefore ask you for identification.

From the moment you withdraw your consent or make an objection, your data will no longer be collected and stored in the national SHM database for national HIV monitoring and your personal data will be anonymised. Data that have already been used in research are anonymous and can no longer be removed. Your HIV treating physician or HIV nursing consultant can tell you more about this process.

Withdrawing your consent or making an objection will not affect your further treatment at the HIV treatment centre.

If you are not satisfied with the way your rights have been handled, you can always submit a complaint to the Personal Data Authority:

www.autoriteitpersoonsgegevens.nl.

Questions, complaints, or further information

If, after reading this letter, you still have questions, a complaint or would like more information, you can discuss this with your HIV treating physician or HIV nursing consultant.

If you have general questions about national HIV monitoring by SHM, please visit our website www.hiv-monitoring.nl. Here you will find more information about who we are and what we do.

If you have any questions about privacy, you can contact our Data Protection Officer:

Contact details SHM

Stichting HIV Monitoring (SHM)

Data Protection Officer

Meibergdreef 9

1105 AZ Amsterdam

Tel: +31205664172

E-mail: privacy.shm@amsterdamumc.nl

Website: www.hiv-monitoring.nl

Chamber of Commerce number: 34160453

Informed consent form

1. If, after you have read this information letter, you wish to take part in the national HIV monitoring programme, you must give your explicit consent. You can give verbal permission to your HIV treating physician or HIV nursing consultant to allow your data, as described in this information letter, to be collected by a data collector.
2. Your HIV treating physician or HIV nursing consultant will record your verbal consent in your medical file. Data collection will only start after this consent has been verified by SHM.
3. Your participation is voluntary and you are aware that you can stop your participation at any time by withdrawing your consent. You do not have to give a reason for this.