

Information letter for hepatitis C research participants

You received the information below by post or at the treatment centre before you gave your written permission for sharing your medical data with Stichting hiv monitoring (SHM).

Why registration and Hepatitis C research

To improve the treatment and prognosis of hepatitis C, practitioners (gastroenterology physicians and internist-infectiologists) want to collect data from people with (cured) hepatitis C in a national registration system.

Despite significant advancements in the treatment of viral hepatitis in recent years, resulting in the potential cure of hepatitis C of nearly everyone, this improvement is not reflected in statistics. Insights on numbers of infections and the course and consequences of hepatitis C is lacking.

As hepatitis C can ultimately lead to severe liver problems, sometimes resulting in death, the government, in the National Hepatitis Plan, recommended establishing a national database with registration data of patients with hepatitis C in the Netherlands.

Your treatment centre has been asked to undertake this registration. For this registration, a collaboration has been established with SHM (www.hiv-monitoring.nl) SHM has extensive experience in nationwide registration of people living with HIV and possesses a digital database that meets the requirements for data security.

Why we are contacting you

In the past you have been treated at the Gastroenterology and Hepatology Department or Internal Medicine for your chronic hepatitis C. You may even have been cured. During these visits, data related to your hepatitis C infection has been stored in your electronic patient record. We would like to use your data for national scientific research on hepatitis C.

If you still visit the clinic for follow-up, these (future) data will also be collected for national scientific research on hepatitis C.

This letter requests your explicit consent for the use of your data for scientific research on hepatitis C. In this letter, you will read more about the research and how to provide your consent.

This letter further informs you about:

- Why and how your data in a participating hepatitis C treatment centre are collected and checked for accuracy;
- Which data will be collected in the context of the hepatitis C research and how your privacy will be safeguarded;
- Where and how the data will be stored;
- With whom your data will be shared;
- How you can indicate that you no longer give consent for the collection of your data;
- What rights you have regarding your data;
- Where you can obtain more information and ask questions.

Why your data is being collected

Your data will be used by your treatment centre for national hepatitis C monitoring and scientific research.

The results of this research contribute to the improvement of hepatitis C care in the Netherlands by increasing knowledge about hepatitis C and its prevention and treatment. This provides insight into effective treatments; reducing problems resulting from Hepatitis C, changes in the annual number of hepatitis C diagnoses in the Netherlands, and other information relevant to the prevention and treatment of hepatitis C.

Where and which data will be collected and how will SHM safeguard your privacy?

The collection of your data and quality controls take place in your treatment centre. After you have given consent, the SHM data collector gathers relevant data from your electronic patient record. The SHM data quality officer performs quality checks on this data by comparing information from your electronic patient record with the data recorded in the national database.

A comprehensive list of all collected data can be obtained from your healthcare provider.

If you give consent, the following data will be collected:

- Date of birth;
- Initials (max. 2 letters);
- Gender;
- Nationality and country of birth;
- 4 digits of the postal code (no letters);
- Any previous registration with SHM if you were treated in another hospital for hepatitis C before;
- Hospital registration number;
- Your consent for the collection of your data.

Your data will be recorded under a unique code number in the national SHM database. Under this code number, the SHM data collector gathers data relevant to national hepatitis C monitoring. This includes data such as symptoms, complaints, treatment, laboratory data, and other examinations such as ultrasound and FibroScan results.

Only the SHM data collector, the SHM data quality officer, and the healthcare provider can trace this code number back to you as an individual.

How your data is stored

Your data is stored in the secure SHM database. Those who have access to this database all have a (medical) duty of confidentiality. SHM employs strict access and security measures. Data exchange is always encrypted to optimize your privacy protection.

With whom data is shared

SHM provides only **non-directly identifiable data** to research institutions. This happens only after a submitted research proposal has been reviewed and

approved, and only if these institutions meet **strict legal and ethical conditions**. Only data necessary for research is shared. Clear agreements are made with the involved institutions regarding the use of these non-directly identifiable data. The data can only be used for the approved research, not shared with others, and must be deleted after the research is concluded.

Data processed in publications of research results are anonymous and cannot be traced back to you as an individual. This ensures compliance with privacy legislation and medical research regulations by your treatment centre and SHM. SHM does not provide data to commercial entities, such as insurers or pharmaceutical companies.

How long will your data be stored?

With your consent, your data will be stored for the duration of national hepatitis C monitoring in the Netherlands.

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 your treating physician that you are withdrawing your consent, making an objection, or exercising another right.

When you exercise your rights, the treating physician 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 hepatitis C monitoring. Data that have already been used in research are anonymous and cannot be removed. Your treating physician 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.

If you have any questions, complaints, other privacy questions or would like more information after reading this letter, you can discuss this with your physician and/or SHM hiv.monitoring@amsterdamumc.nl.

For general questions about the national hepatitis C monitoring, please contact SHM hiv.monitoring@amsterdamumc.nl.