Invitation to participate in the Norwegian Quality Registry for HIV (NORHIV)

Background and purpose

We are inviting you to participate in the National Quality Registry for HIV to ensure the quality of treatment of patients with HIV infections. Everyone with HIV in Norway is being asked to submit data to the registry. The quality registry project was initiated by Oslo University Hospital (OUS). The day-to-day operations and data processing responsibility have been assigned to OUS under the auspices of the Infectious Diseases Department.

What does participation in the Norwegian Quality Registry for HIV entail?

The information about you which is stored in the registry concerns your diagnosis and situation regarding your disease, when you started and possibly stopped HIV treatment, what medications you are taking, whether you have other medical conditions relevant to your HIV infection and whether you may have been treated for these (such as heart disease, cancer, tuberculosis, and hepatitis B or C). You will also be asked to complete a questionnaire about your health and how you experience the health care you receive. More detailed information about what is registered about you can be found on the registry's website: https://www.kvalitetsregistre.no/register/andre/norsk-kvalitetsregister-hiv

Advantages and disadvantages

The Quality Registry will give us a better overview and understanding of the lives and treatment of patients living with an HIV infection. If we see higher frequencies of some particular diseases and ailments in those living with HIV, we can increase awareness of these conditions and be able to provide better medical follow-up. The registry only contains a systematisation of previously documented medical information about you and does not entail any additional blood tests, examinations or treatment. The fact that information is systematised in a registry may be perceived by some as a disadvantage. The registry therefore has strict requirements for protecting this information. It has been approved by the data protection officer at OUS.

What happens to the information we gather from you?

The information recorded about you is used only as described in this information. Only a few people associated with the registry have access to your national identity number. The information is treated confidentially and those who have access to it have a duty of confidentiality. All information about you that is used in any report or study will be processed without you being identified. This means that all information will be processed without names and national identity numbers or other directly identifiable personal information. A code links you to your information through a link list. You have the right to access the information registered about you and to read applicable security measures when the information is processed.

It may be appropriate to compare information from the registry with the following public registries:

- Norwegian Population Registry
- Norwegian Patient Registry
- The Cause of Death Registry
- Cancer Registry of Norway
- National Hip Fracture Registry
- Norwegian Renal Registry
- Norwegian Cerebral Infarction Registry
- Norwegian Myocardial Infarction Registry

- Tuberculosis Registry
- Birth Registry
- National Vaccination Registry SYSVAK
- Norwegian Prescription Database
- National Pandemic and Intensive Care Registry (NIPaR)

The reasons for compiling information from the Norwegian Quality Registry for HIV and these 13 public registries is described in more detail in Chapter B.

The information in the registry may also be used for medical and health research. One prerequisite is that a research project must be approved by the Regional Committee for Medical and Health Research Ethics (REK), and that it is in line with the purposes of NORHIV. The information may be disclosed as anonymous (de-identified), i.e. without name and national identity number, to researchers both in Norway and abroad in accordance with the REK approval. With a connection key, it will be possible to link the clinical information about you to the registries mentioned above. NORHIV's professional council, where users are also represented, must always approve the disclosure of information and verify that the research project complies with the terms of consent that you provide here.

The information in the registry is stored until 2030. If it proves necessary, the registry will apply for an extension. Then the information will be stored as long as the registry exists, or until you withdraw your consent.

Voluntary participation
Participation in the Quality Registry is voluntary. There will be no negative consequences for your treatment or your relationship with the health services if you choose not to participate. If you wish to participate, please sign the Declaration of Consent on the last page. You may withdraw your consent to participate in the Quality Registry at any time and without giving any reason. This will not affect further treatment. If you wish to withdraw or have any questions about the project, please contact [enter name, telephone number and e-mail address of the project manager, or other permanent contact person]. It should be just as easy for the participant to withdraw as it is to give consent.
Further information about the study can be found in *Chapter A* – *in-depth explanation of what the study entails.*
Further information on privacy and your rights can be found in Chapter B – *Privacy, Financing and Insurance.*
The Consent Form is found in Chapter B.

Chapter A – in-depth explanation of what the Quality Registry entails

- **Criteria for participation: everyone with a HIV infection in Norway**

- **Background information for the Quality Registry**

The Norwegian Quality Registry for HIV was established by Oslo University Hospital. The purpose of the registry is to monitor and improve the quality of follow-up and treatment of patients with HIV at Norwegian hospitals. The purpose of the registry is also to ensure equal and comprehensive follow-up of everyone living with HIV in Norway. We want to improve the diagnosis and treatment of HIV and to promote research related to HIV. The following items will be relevant for reporting from the Quality Registry and for possible research projects:

1) study the clinical efficacy of current HIV treatment
2) identify the incidence of possible side effects of HIV medications
3) reveal whether there is a higher frequency of particular diseases and ailments among those living with HIV compared to the general population.
4) map resistance conditions (both viruses and bacteria) in patients with HIV
5) map the quality of follow-up of patients at the country's HIV clinics. The starting point for follow-up will be the current national guidelines for the follow-up of people living with HIV.

- **Alternative procedures or treatment if you choose not to participate in the registry**

All information registered in the Quality Registry must also be registered in your medical records. There will therefore be no other procedures or treatment for those who are not included in the registry.

- **Examinations and blood tests**

Participation in the registry does not require any additional examinations, blood tests or attendance than is ordinary for monitoring the disease, but you will be asked to complete an additional questionnaire.

Chapter B – Privacy, Financing and Insurance

Privacy

Information recorded about you in the National Quality Registry is information about diagnoses and information describing the situation surrounding your disease. Examples of recorded information are: date of first positive HIV test, date of last negative test, assumed location of infection and mode of infection, country of birth, gender, other diseases, vaccines, HIV medicines you use and have used previously, side effects of these, resistance to HIV medicines, blood tests (including CD4 figures, HIV RNA, cholesterol, kidney function and long-term blood glucose), your answers to questionnaires, possible pregnancy and smoking habits. A complete overview can be found on the registry's website.

The information collected may be used for research by linking information from one or more of the public registries mentioned below. Such a project must be assessed and approved in accordance with applicable rules in addition to this consent; see the detailed description below.

The Registry	Reasons
Norwegian Population Registry	This registry is used to update your national identity number/death/emigration in the Quality Registry for HIV.
Norwegian Patient Registry (NPR)	It will be possible to check whether the number of patients in the local registry corresponds to the number of patients registered with HIV in the Norwegian Patient Registry (NPR). All contacts with the specialist health services are registered in NPR with diagnoses and national identity number.
Cause of Death Registry	This registry allows us to track the deaths of our participants, and know what they died from. This may be important in order to determine whether HIV patients, for example, are at increased risk of suicide, or whether the group has a higher mortality rate associated with individual diagnoses than the general population.
The Norwegian Cancer Registry	This registry allows us to find out whether people with HIV have a higher incidence of certain types of cancer, as well as whether the course of treatment stands out compared to other patients with the same cancer diagnosis.
Norwegian Hip Fracture Registry	This registry allows us to find out whether people with HIV have hip fractures more often than the rest of the population.

National Kidney Registry	This registry allows us to find out whether people with HIV suffer more from renal failure more often than the rest of the population.
Norwegian Cerebral Infraction Registry	This registry allows us to find out whether people with HIV suffer more from cerebral stroke more often than the rest of the population.
Norwegian Myocardial Infarction Registry	This registry allows us to find out whether people with HIV suffer more from myocardial infarction more often than the rest of the population.
Tuberculosis Registry FHI	This registry allows us to find out whether people with HIV suffer more from tuberculosis more often than the rest of the population.
Medical Birth Registry NIPH	This registry allows us to find out whether the children of people with HIV are doing as well as other children in Norway.
Norwegian Immunisation Registry SYSVAK FHI	This registry allows us to find out which vaccines have been given to people with HIV.
Norwegian Prescription Database (NorPD)	This registry allows us to find out which prescriptions have been written for people with HIV.
National Pandemic and Intensive Care Registry (NIPaR)	This registry allows us to look at the risk of severe COVID-19 and COVID-19 related hospitalisations in people with HIV.

A more detailed description of these registries can be found online: www.kvalitetsregistre.no or www.helsenorge.no/helseregistre. Here you will also find more information about data protection and the regulations related to medical quality registries and public health registries.

It may be appropriate for the National Quality Registry to contact the nurse (or doctor) who is the contact person for a local registry to clarify whether information registered about you in the national registry corresponds to what is stated in the records. This will only be information corresponding to what is mentioned in the variables list. The purpose here is to make sure the information in our registry matches the corresponding information in your medical records. One example of this could be that the nurse in your ward has registered that you weigh 150 kg. Then we may need to check whether this is really true.

Oslo University Hospital functions as the data controller for NORHIV.

Studies linked to regulatory registries

If you agree to participate in the quality registry, you also give your consent to have your information linked to the 13 registries named and mentioned above. The link should comply with the reasons formulated for each registry. The individual research projects will also have to be approved by the

Regional Committee for Medical and Health Research Ethics (REK). Disclosure of data must be approved by the NORHIV Professional Council where users are also represented; also see the description in NORHIV's Articles of Association

Right to access and delete information about you

If you agree to participate in the registry, you have the right to access the information registered about you. You can do this in an easy way by requesting to speak to [local contact person for the individual health trust is provided here] to get a review of the data registered on you. All your information in NORHIV will be entered locally at the HIV clinic that monitors you on a regular basis. These people can also correct your data if something is recorded incorrectly. You may at any time, and without giving any reason, withdraw your consent to participate in NORHIV by contacting the person named above (see contact information above). All collected information about you in NORHIV will then be deleted. This will not affect further treatment. In the long term, we hope that you will also be able to withdraw your consent via login in the Consent Module in Helsenorge.no. You can contact the Norwegian Data Protection Authority (phone 22 39 69 00) or the Norwegian Board of Health Supervision if your health information is not processed in accordance with the Regulations relating to Medical Quality Registries or other relevant regulations. You can also contact the data protection officer at Oslo University Hospital (personvern@oslo-universitetssykehus.no) if you have questions about the processing of your personal data in the registry.

Financing

The registry is approved as a national quality registry, so funds for operation are allocated annually in accordance with procedures for national registries. The registry has been awarded funding from the Southern Norway Regional Health Authority for operations and from the Center for Clinical Documentation and Evaluation (SKDE) for the development of ICT solutions (MRS) under the auspices of HEMIT.

Information on accumulated registry data

Participants in the registry have the right to obtain information from the registry. Annual reports and results from NORHIV will be published annually, which you can read on the registry's website: https://www.kvalitetsregistre.no/register/andre/norsk-kvalitetsregister-hiv

Annual information meetings are planned for participants and user organizations.

Consent to participate in the NORHIV Quality Registry

I am willing to participate in the NORHIV Quality Registry

(Signed by user, date)

Proxy consent when warranted, either in addition to the person himself or instead

(Signed by next of kin or close family member, date)

I confirm that I have provided information to the NORHIV Quality Registry

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(Signed, role in NORHIV, date)