EuroSIDA *Sample* Informed Consent

Sample **Patient Information and Informed Consent for the EuroSIDA study, version 4.0, dated 5 July 2019**

Protocol title: EuroSIDA **-** Clinical and virological outcomes for European people living with HIV

Dear Patient,

We would like to ask you if you will be willing to participate in **the EuroSIDA study.**

What is the study about
EuroSIDA is an observational study that has been ongoing since 1994 and where we currently follow over 22,000 people living with HIV in clinical care across Europe. In the study we gather clinical, therapeutic, demographic, virological and laboratory data to investigate the long-term prognosis and outcomes for the patients.

Who is eligible for this study
Patients 18 years of age or older living with HIV-1 under follow-up.

What will happen in the study
After your enrolment visit (today) staff members in your clinic will fill in a questionnaire with data on your gender, age, date of HIV diagnosis, relevant routine laboratory data, medical treatment and co-infections. These data will be extracted from your patient record.

Hereafter once annually (October), data from your routine visits to your clinic, information on medical history, laboratory measurements, treatment and possible symptoms and illnesses associated with your HIV-infection and other possible co-infections will be collected from your patient records. In case of certain clinical events an additional form will be filled out. In addition, we kindly ask you to provide 5-10 ml of blood.

This study does not test any drugs and will not interfere with any treatment you may receive at this clinic.

Risk and benefits
Participation in EuroSIDA study does not include any additional risks for you. There is no personal benefit from participating, However, the study seeks to improve knowledge about HIV long-term prognosis to improve treatment guidelines and care and treatment for people living with HIV or AIDS.

You will not be compensated for your participation in the EuroSIDA study.

Who is leading the research
Over 300 investigators are part of the EuroSIDA study, which is governed by an elected Steering Committee of 17 members with broad geographic representation.

Sponsor and study coordinator is CHIP, which is an independent research institution at the Department of Infectious Diseases at Rigshospitalet in Copenhagen, Denmark.

EuroSIDA is a founding partner in the RESPOND International Cohort Consortium of Infectious Diseases and submits pseudonymized data to the RESPOND consortium data repository 'data lake', which is stored in a central database. If you participate in the EuroSIDA study, you will also have to accept to participate in RESPOND and sign the Informed consent form for RESPOND.

How is the study financed

EuroSIDA has received funding from ViiV Healthcare LLC (1.247.500€), Janssen Scientific Affairs, Janssen R&D (187.500€), Bristol-Myers Squibb Company (450.000€), Merck Sharp & Dohme Corp (240.000€), Gilead Sciences (268.000€) and the European Union's Seventh Framework Programme for research, technological development and demonstration under EuroCoord grant agreement n˚ 260694 (3.750.000€). The participation of centres from Switzerland has been supported by The Swiss National Science Foundation (Grant 148522). The study is also supported by the International Cohort Consortium of Infectious Disease (RESPOND).

What happens to my data

During the study all information and blood samples collected from you will be de-identified and a unique patient identification study number will be assigned to you. All efforts will be made to keep your information confidential and only staff at this clinic are able to identify you.

The pseudonymized data from your patient record and collected blood will be sent to the coordinating centre (CHIP) at Rigshospitalet in Copenhagen, to be stored together with similar data from several thousands of other European patients living with HIV. All data will be stored in accordance with current EU legislation. All the data we have collected about you in the EuroSIDA study will be part of the RESPOND common data repository or 'data lake'. For further information see the RESPOND Informed Consent.

The information and blood collected will be analysed in accordance with the scientific programme in EuroSIDA to study the HIV infection and associated diseases. As EuroSIDA researchers physically are located at different European universities and hospitals, datasets containing information from your medical record and blood sample analysis might be analysed at other locations than at the EuroSIDA coordinating centre (see annex). The data will not contain information that can be used to identify you as your data will be pseudonymized.

You will be asked to give permission to allow restricted access to your medical records. They may be inspected by EuroSIDA study monitors or a government authority to ensure that the study is being carried out correctly.

What if I change hospital

If you move or transfer your medical care to another hospital participating in EuroSIDA, the research staff would like to continue to collect information for the study.

With your permission, your doctor will contact your new hospital and ask them to continue follow-up in EuroSIDA at this new institution.

How to withdraw

This study does not in any way interfere with the current or future treatment and care that you are receiving at this hospital. Your participation in this study is completely voluntary, and you can at any time decide to withdraw your participation. Should you choose to withdraw your participation, this will have no consequences for your treatment and care.

Contact person regarding EuroSIDA at this clinic is:
Name: _____
Department: _____
Phone: _____

This study and information sheet have been reviewed by the XXX Ethics Committee (EC reference number).

- I confirm that I have read and understand the information sheet above and have been given the opportunity to ask questions and these have been answered to my satisfaction.
- It has been explained to me that participation is voluntary, and I am free to withdraw from the study at any time and for any reason, without prejudice to my treatment or any other rights.
- I permit that authorised personnel may review my personal information, but identifiable information will under no circumstances be made publicly available.
- I have been given a copy of the information sheet.
- I have been informed of the appendix containing more information about the processing of my personal data and my rights as a registered cf. GDPR art. 13
- I agree that the data collected in the EuroSIDA study can be part of the RESPOND consortium datalake
- I agree to participate in the EuroSIDA study.

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NAME OF PATIENT	SIGNATURE OF PATIENT	DATE
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NAME OF RESEARCHER	SIGNATURE OF RESEARCHER	DATE