***Sample* Patient Information and Informed Consent for RESPOND, version 1.0, dated 07 July 2017**

We would like to ask you if you would be willing to participate in the RESPOND study.

**Protocol title**: International Cohort Consortium of Infectious Diseases, RESPOND

**Purpose**The aim of the International Cohort Consortium of Infectious Diseases (RESPOND) is to build an innovative, flexible and dynamic cohort consortium for the study of infectious diseases, including HIV and people at risk for HIV, as a generic structure for facilitating multi stakeholder involvement. This consortium builds upon the outstanding collaborative work in HIV cohort studies that has taken place in Europe and beyond over the last 20 years and which has provided crucial information contributing to the improvement in the lives of HIV-positive individuals. RESPOND will continue to answer the most important questions of interest to the infectious diseases research community

The RESPOND study is coordinated by CHIP, which is an independent research institution at the Department of Infectious Diseases at the State University Hospital (Rigshospitalet) in Copenhagen, Denmark. RESPOND is governed by the RESPOND Executive Committee.

RESPOND is funded by ViiV and Gilead as well as participating cohorts, including EuroSIDA and the Australian HIV Cohort, with a total budget of 7 million Euro in 2017-2021.

**Study procedures**Data will be collected at the time you are enrolled in the study, and once a year hereafter. The data recorded are extracted from your patient record by staff at your clinic who works with the RESPOND study. Interviews with you may also be performed to collect data.

Data collected will be: Demography and basic information, relevant routine laboratory data, medical treatment, clinical events and additional data about alcohol, smoking and drug use.

**Risk and benefits**Participation in the RESPOND study does not include any additional risks for you. The study does not test any drugs or and will not interfere with the treatment or care you may receive at the clinic. There are no direct benefits for you. However, the study seeks to improve knowledge about HIV and associated diseases leading to improved guidelines for managing treatment and care for people living with HIV. All RESPOND publications and presentations will be listed on the CHIP webpage, [www.chip.dk](http://www.chip.dk)

**Confidentiality**During the study all information collected from you will be coded and identified by a unique study number. All efforts will be made to keep your information confidential and no persons outside this hospital are able to identify you based on the information submitted. Any publication of this study will not use your name or identify you personally.

All data at the coordinating centre is stored and protected in accordance with current EU legislation.

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

**Transfer**

If you move or transfer your medical care to another hospital participating in RESPOND, 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 RESPOND at this new institution.

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 RESPOND at this clinic is:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This study and information sheet has 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 agree to participate in the RESPOND study.

.................................................. .................................................... ........./......../........

NAME OF PARTICIPANT SIGNATURE OF PARTICIPANT DATE

.................................................... ................................................... ......./......../..........

NAME OF RESEARCHER SIGNATURE OF RESEARCHER DATE