***Sample* Patient Information and Informed Consent for RESPOND, version 1.0, dated 27 May 2019**

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

*Dear Patient,*

You have agred to be part of a study in the RESPOND consortium and we would like to ask your permission to store your pseudonymised non-identifiable data in the RESPOND database or “data lake”.

**What is RESPOND**

RESPOND is a collaboration and a structure enabling all studies in RESPOND to store the collected study data in a common data repository or ‘data lake’, which is stored in a database. The data collection itself is modular, with a common core module consisting of data collected for most participants participating in studies in RESPOND and data from specific studies consisting of targeted data collection for subgroups of participants. You can be part of one or more studies in the RESPOND consortium.

**Participation in RESPOND**

Your data collected for the data repository is described in a separate Patient Information for the study you take part in and you will be asked to sign a separate Informed Consent for that. All information collected from you will be de-identified and a unique Patient Identification number will be assigned to you. All efforts will be made to keep your information confidential and only study staff at this clinic are able to identify you. The pseudonymised non-identifiable patient data will be stored in the RESPOND database and may be used for future scientific research projects.

You will not be compensated for your participation in the RESPOND data lake.

**The aim of RESPOND**

The aim of RESPOND is to build an innovative, flexible and dynamic 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. RESPOND is governed by the RESPOND Executive Committee. All RESPOND publications and presentations will be listed on the CHIP webpage, www.chip.dk

**Who is the study sponsor**

Sponsor and coordinator of RESPOND is CHIP, which is an independent research institution at the Department of Infectious Diseases at the State University Hospital (Rigshospitalet) in Copenhagen, Denmark. All data in the RESPOND data repository is stored and protected in accordance with current EU legislation and approved by the Danish Data protection Authority.

**Who are the funders**

RESPOND has received funding from ViiV Healthcare LLC and Gilead Sciences. Additional support has been provided by participating cohorts contributing data in-kind and/or statistical support: Austrian HIV Cohort Study (AHIVCOS), The Australian HIV Observational Database (AHOD), CHU Saint-Pierre, University Hospital Cologne, The EuroSIDA cohort, Frankfurt HIV Cohort Study, Georgian National AIDS Health Information System (AIDS HIS), Modena HIV Cohort, San Raffaele Scientific Institute, Swiss HIV Cohort Study (SHCS), and the Royal Free HIV Cohort Study.

**Access to medical records**

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.

**Participation and withdrawal**

Your participation in RESPOND is completely voluntary. You can choose not to participate. If you chose to participate you can at any time decide to withdraw your participation. This will have no consequences for your treatment and care. If you decide to withdraw from RESPOND, you will also withdraw from studies under the RESPOND consortium.

Contact person regarding RESPOND at this clinic is:

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

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

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

* 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 this 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 my data collected in a study in RESPOND is stored in the RESPOND database for future scientific research projects.

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NAME OF PARTICIPANT SIGNATURE OF PARTICIPANT DATE

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NAME OF RESEARCHER SIGNATURE OF RESEARCHER DATE