# Appendix 2 - *Sample* Informed Consent

***Sample* Patient Information and Informed Consent for the RESPOND Outcomes Study, version 2.0 dated 29 May 2019**

**Protocol title:** The RESPOND Outcomes Study

*Dear Patient,*

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

**What is the study about**

In the Outcomes study we are recruiting people living with HIV. We want to investigate the long-term outcomes of different antiretroviral therapies and other relevant drugs. Data collected in this study will be used to answer key unanswered questions regarding people living with HIV treated with newer antiretroviral treatment (ART) drugs. Focus is on investigating the safety of the drugs, long term outcomes and any clinical disease progression.

**Who is eligible for this study**

Patients 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 (in October), data from your routine visits to this 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.

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 Outcomes 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 and antiretroviral treatment monitor outcomes and evaluate safety 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 Outcomes study.

**Who is leading the research**

The Outcomes Study is a study in the RESPOND International Cohort Consortium of Infectious Diseases. The study has been initiated by the RESPOND Outcomes Scientific Interest Group (SIG) which is responsible for the scientific aspects of the study. For further information see the RESPOND Informed Consent.

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

**Who finances the research**

RESPOND and the Outcomes study has received funding from ViiV Healthcare LLC [2 million Euros] and Gilead Sciences [2 million Euros].

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.

**What happens to my data**   
During the study all information collected from your patient file 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.

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

If you participate in the Outcomes study, you will also have to accept to participate in RESPOND and sign the Informed consent form for RESPOND. All the data we have collected about you in the Outcomes study will be part of the RESPOND common data repository or ‘data lake’. For further information see the RESPOND Informed Consent.

You will be asked to give permission to allow restricted access to your medical records.

Your records may be seen by:

* Institutional Review Boards (IRBs) or Ethic Committees (ECs) who review the study to make sure it is ethically acceptable
* Research staff and study monitors, and their designees.

**What if I change hospital**

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.

**How to withdraw**

Your participation in this study is completely voluntary, and whether or not you participate will have no consequences for your treatment and care. You can at any time decide to withdraw your participation and should you choose to withdraw your participation, you can tell your clinic to tell us to remove your record at any time.

Contact person regarding the Outcomes study at this clinic is:

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

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

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

This study and information sheet have been reviewed by the Danish Scientific Ethics Committee.

* 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 Outcomes study can be part of the RESPOND consortium.
* I agree to participate in the Outcomes study.

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Name of participant Signature of participant Date

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Name of Researcher Signature of Researcher Date