Appendix II - *Sample* Informed Consent

***Sample* Patient Information and Informed Consent for the CARE East Cohort in RESPOND, version 1.0 dated 16 August 2019**

Protocol title: CARE East Cohort study

Dear Patient,

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

What is the study about
In the CARE East Cohort study we are recruiting people living with HIV regardless of CD4 cell count and ART status; and people living with HIV positive for anti-HCV regardless of HCV-RNA, fibrosis stage and prior HCV therapy.

It is an observational cohort study with the overall objective to explore the uptake and clinical impact of anti-viral therapy in Eastern European patient populations and the clinical outcomes in people living with HIV or HIV/HCV. The study will include both standardised clinical data based on local routine data collection will take place at enrolment and at a follow-up visit.

Who is eligible for this study
Patients living with HIV and/or HCV 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 the CARE East Cohort 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, HCV and antiretroviral treatment monitor outcomes and evaluate safety to improve treatment guidelines and care and treatment for people living with HIV/AIDS or HCV.

You will not be compensated for your participation in the CARE East Cohort study.

Who is leading the research
The CARE East Cohort study in RESPOND has been developed within the framework of the CARE project, which runs for two years (2019 and 2020) and is a collaboration between investigators from clinics across EU, Georgia, Russian Federation and Ukraine. The CARE East Cohort is set-up of as a study in the RESPOND International Cohort Consortium of Infectious Diseases. This is an important step towards sustainability of the collaborations beyond the duration of the CARE project. For further information see the RESPOND Informed Consent.

RESPOND 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
This project has received funding from the European Union's Horizon 2020 Research and Innovation programme under Grant Agreement No 825673.

The RESPOND consortium 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 study information is pseudonymized and only staff at this clinic can identify you. All data at the coordinating centre is stored and protected in accordance with current EU legislation.

If you participate in the CARE East Cohort, 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 CARE Cohort 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 or Ethic Committees who review the study to make sure it is ethically acceptable
- Research staff and study monitors, and their designees.

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.

Your participation in this study is completely voluntary, and whether 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 CARE Cohort 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 CARE Cohort study.

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

Name of participant [or Participant ID in Ukraine]	Signature of participant	Date
.....	.....	...../...../.....
Name of Researcher	Signature of Researcher	Date

Appendix III Data Protection
Information to be provided in relation to the EU's General Data Protection Regulation, GDPR, Article 13

As a participant in the CARE East Cohort study in RESPOND, please find the description below of the procedures in connection with collection and protection of your data, as well as your rights regarding the data collection, in case this is not described in the Patient Information.

Purpose and legal basis for the processing of your personal data
We will use your personal data for the purpose described in the Patient Information.

The legal basis for our processing of your personal information follows from:

- Permission from the Danish Scientific Ethics Committee, cf. the Danish Act on the Scientific Ethical Treatment of Health Science Research Projects with the consent of the data subject.
- Consent from you to obtain information from your journal as an authorized healthcare professional for use in the specific project, cf. Section 42d (1) of the Danish Health Act. The subsequent processing and storage follow from the consent requirements of Articles 6 and 9 of the General Data Protection Regulation and preamble 32-33.

Categories of personal data
We only process the personal data related to you that are described in the Patient Information.

Data processors
We process your data for the described purpose of the study. We may securely share your data with other investigators for processing related to the study. The data shared are pseudonymised. Investigators comply with the same laws and policies to protect your data as we do.

The following are external data processors who, on our behalf, process your data for the study purposes:

- Computerome: Server/it-system
- IrsiCaixa: Bioinformatics analyses
- Swiss HIV Cohort Study: Biostatistical analyses
- University College London: Biostatistical analyses
- Kirby Institute: Statistical analyses

For further information regarding the data processors, please contact the primary project responsible.

Transfer to new data controller
If we are contacted by another data controller for disclosing project data about you, we will, prior to the disclosure of your data, contact you for consent to transferring your information to a new data controller for their individual use.

From where do we collect your personal data?
It is described in the Participant Information from where we have collected your personal data.

Storage of your personal data
At the present moment we cannot confirm for how long your personal data will be kept on file. However, when it is decided for how long your data will be kept on file, importance will be attached to: the study period; the time needed for data analyses to be able to answer the purpose described in the participant information; and the period of time the authorities in the participating countries require that the information is kept on file after the study is completed.

The right to withdraw consent
You have the right to withdraw your consent from the study at any time. To do that contact the study team at your site.

If you chose to withdraw your consent, we will still be able to use your personal data already collected on basis of your previous consent up until the time of withdrawal. If you withdraw your consent, it will have effect from the time of withdrawal and onwards.

Your rights
According to General Data Protection Regulation you have several rights in relation to our processing of your personal data.

If you want to use your rights, please contact the person responsible for the study.

Right to deletion of data
Special regulations apply in relation to statistical and scientific investigations, including research cf. General Data Protection Regulation article 17, paragraph 3, litra d. This means that we can keep on file and use the data we have already collected to assure that study results are accurate.

Right to transfer data (data portability)
In some cases, you have the right to receive your personal data in an organised, regularly used and machine-readable format and to have these personal data transferred from one controller to another without hindrance.

Some rights are exempt in statistical and scientific investigations, including research
This is to assure that the study results are accurate and not biased.

Complaints to the Data Protection Agency
You are entitled to file a complaint to the Data Protection Agency in case you are unsatisfied with the way we process your personal data. You can find contact information to the Data Protection Agency here: www.datatilsynet.dk/english/

Contact information

Primary project responsible
The primary project responsible is the person responsible for the execution of the study:

Primary project responsible Prof. Jens Lundgren.
Contact person Stine Jakobsen
Rigshospitalet, University of Copenhagen

CHIP, Department of Infectious Diseases, Section 2100
Finsencentret
Blegdamsvej 9
DK-2100 Copenhagen Ø, Denmark
Telephone number: +45 35455793
E-mail: care.rigshospitalet@regionh.dk

Data controller

Region Hovedstaden is data controller of the processing of your study data:

Region Hovedstaden/ v. Videnscenteret for Dataanmeldelser
Blegdamsvej 9
DK-2100 Copenhagen Ø, Denmark
E-mail: videnscenteretfordataanmeldelser.rigshospitalet@regionh.dk