
# RESPOND

## International Cohort Consortium of Infectious Diseases

## Version 1.0 May 2019

**Sponsor and Coordinating Centre:**

**Rigshospitalet - University of Copenhagen**
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# 1. SUMMARY

**Full title of project:** International Cohort Consortium of Infectious Diseases (RESPOND)

**Acronym of project:** RESPOND

**Summary**:
The International Cohort Consortium of Infectious Diseases (RESPOND) is a consortium collecting retrospective and prospective observational cohort data. The aim of RESPOND is to build an innovative, flexible and dynamic cohort consortium and a large data repository for the study of infectious diseases, including HIV, as a generic structure for facilitating multi stakeholder involvement. In RESPOND there are different studies organized under thematic modules.

All data collected in studies in RESPOND is pooled in a common data repository or 'data lake', which is stored in a database. However, the data collection itself is project-based or modular, with specific studies consisting of targeted data collection for subgroups of participants. A participant can be part of several specific studies. All sites/centres will collect data to one or more specific studies depending on their participant inclusion. Pseudonymised patient data can be entered manually via a secure online browser-based platform or be transferred electronically from existing local, regional or national data structures to the data repository.

The common data repository allows for important cross-cutting research across modules and studies, with important synergies, and costs savings in terms of data collection. For most participants in RESPOND core data is collected for the following categories: Demography and basic clinical information; Relevant virological and immunological information; Laboratory information regarding organ function and biomarkers for metabolic illness, Co-infections including genotype and relevant paraclinical information; and Antiretroviral Treatment (ART) information.

The RESPOND Scientific Steering Committee (SCC) is an independent body responsible for overseeing the scientific output of the different data modules, and approving initiation of new specific projects. The SSC comprises 2 co-chairs, representatives from the coordinating center, 1 representative from each cohort submitting data to the study, the 2 leads of each Scientific Interest Group, community representatives, and external experts as agreed by the SSC. This includes researchers, statisticians, clinicians as well as representation from the HIV community.

Studies in RESPOND are conducted under RESPOND SSC supervision and direction of a study specific Scientific Interest Group (SIG). The organizational parts of the RESPOND Cohort Consortium is governed by an Executive Committee constituted by a broad group of stakeholders.

**Study start date** (date open for recruitment or date of first participant enrolled)

# 2. PROJECT PURPOSE

## 2.1 THE AIM OF RESPOND

The aim of the International Cohort Consortium of Infectious Diseases (RESPOND) is to build an innovative, flexible and dynamic cohort consortium and large data repository 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 people living with HIV. RESPOND will continue with a rigorous approach to answering questions with robust and reliable scientific methodologies as well as having the flexibility and willingness to answer the most important questions of interest to the infectious diseases research community. RESPOND will be based on an extremely successful and highly experienced existing infrastructure, which will be adapted and expanded – including an inclusive network of clinics and cohorts and utilizing the operational infrastructure used for EuroSIDA, DAD, INSIGHT and other key studies, based at CHIP since 1994. The large collaborative nature of RESPOND allows for cross cutting research and synergy for proven methods of data collection in a larger network of stakeholders and data providers.

## 2.2 RESPOND DATA LAKE AND STUDIES

For studies in the RESPOND consortium all collected data is pooled in a common data repository or ‘data lake’, which is stored in a database. However, the data collection itself is project-based or modular, with specific studies consisting of targeted data collection for subgroups of participants. A participant can be part of several specific studies. All sites/centres will collect data to one or more specific studies depending on their participant inclusion. The common data repository allows for important cross-cutting research across modules and studies, with important synergies, and costs savings in terms of data collection. For most participants in RESPOND core data is collected for the following categories: Demography and basic clinical information; Relevant virological and immunological information; Laboratory information regarding organ function and biomarkers for metabolic illness, genotype and relevant paraclinical information; and treatment information.

## 2.3 STUDY OBJECTIVES

RESPOND is a consortium collecting observational cohort data with the objective to allow a quick response to unmet and novel research needs. The flexible structure of RESPOND means that new study areas and research modules can be added easily, where the large network of research experts from around the world will design the research questions for studies in RESPOND.

Studies in RESPOND are conducted under RESPOND SSC supervision and direction of a study specific Scientific Interest Group (SIG). The data repository and database will be subject to agreed Quality Control (QC) checks before approval for research purpose usage. By drawing on the large data repository, studies in RESPOND will be able to answer research questions within a wide range of infectious disease research on both patients living with HIV or other infectious diseases researching pharmacovigilance, commodities, coinfections, biomarkers and public health.

# 3. METHODOLOGY

## 3.1 STUDY DESIGN

Studies in the RESPOND consortium are clinical observational studies that collect retrospective and prospective observational cohort data and, for some studies, biologic samples.

The data collection is modular, with a minimum core data collection for all participants and targeted data collection for subpopulations in studies in RESPOND. The RESPOND common data repository holds all data, that is both core data and specific study data. The studies in RESPOND are defined by SIGs within the RESPOND consortium and may draw on all data within the RESPOND common data repository as well as generating new data.

All centres participating in studies in the RESPOND consortium collect data from their participants at the time of enrolment, and once a year hereafter. The length of the follow up (FU) period is specified in each study protocol. If relevant for the specific study, data on specific clinical events (cancer, stroke, myocardial infarction, invasive cardiac procedure, malignancies, renal failure, liver failure, bone fracture and cause of death) will always be captured in real-time using REDCap.

## 3.2 ENROLMENT

The participants to be included in RESPOND and in studies in RESPOND will depend on the scientific scope and willingness and interest of the participating sites and cohorts. Participating sites/centres can then choose which of the studies they wish to contribute data to. Likewise, existing data structures or ongoing cohorts can enter into collaborations in studies or modules with an individual branded scientific profile depending on interest and involvement.

## 3.3 DATA ITEMS COLLECTED

The following CORE data are collected for most participants in studies in RESPOND: Demography and basic clinical information; Relevant virological and immunological information; Laboratory information regarding organ function and biomarkers for metabolic illness, co-infection including genotype and relevant paraclinical information; and treatment information.

Additionally, project-based or modular defined data is collected with the specific studies in RESPOND some of these collect fewer data items (for details see protocols for the Outcomes Study and the PrEPare Study).

## 3.4 DATA COLLECTION

Study sites/clinics will collect data on participating patients at the time of enrolment, and once a year hereafter. Patient interviews may also be performed in some studies. At the time of enrolment, retrospective data maybe collected up to five years back if relevant and available. Patient record data capture for the Enrolment and FU forms is done by manual data keying or electronically. Manual data keying is performed by site staff in a secure online browser-based platform called REDCap. Electronic data capture entails local extraction of data from clinical electronic databases and submission using the CHIP-developed web-based RESPOND electronic submission tool (REST) to the RESPOND common data repository. Data is submitted in the HIV Cohorts Data Exchange Protocol (HICDEP) format. The RESPOND common data repository is a database located at CHIP, Rigshospitalet, Denmark. For each study in the

RESPOND consortium the specific data items collected are described in the study protocol (for details see protocols for the Outcomes Study and the PrEPare Study).

### 3.5 STUDY MONITORING AND DATA QUALITY

The sponsor and coordinating centre, CHIP, monitors data submitted to the RESPOND data repository and entered in the database for completeness and quality, and query data when needed. Data quality is a top priority for the RESPOND Cohort Consortium. Collected data undergoes extensive quality assurance procedures and six quality assurance (QA) processes are in place:

1. Data quality checks/rules built into the secure online browser-based platform REDCap that automatically detects and notifies when a user has entered in data erroneously, i.e. units measured beyond set limitations, etc.
2. Query lists that detect missing data and/or data that need further clarification or correction.
3. Data cleaning.
4. 100% form assessment on event forms by medical personal
5. Clinical sites may be visited by a monitor appointed by CHIP who will perform on-site monitoring of patient records
6. The web-based tool REST generates a report of errors allowing the site investigator to correct errors before submitting data.

# 4. DATA ANALYSIS METHODS

### 4.1 POWER CONSIDERATIONS

Each study in RESPOND has its own protocol, study plan and data analysis methods developed based on power considerations. By drawing on the large data repository, studies in RESPOND will be able to answer research questions within a wide range of infectious disease research on persons living with HIV and/or other infectious diseases or people at high risk of acquiring HIV researching pharmacovigilance, commodities, coinfections, biomarkers and public health (for details see protocols for the Outcomes Study and the PrEPare Study).

# 5. STUDY SUBJECTS

### 5.1 STUDY POPULATION

The RESPOND study population consists of people at high risk of acquiring HIV and people living with HIV and/or with other infectious diseases or across Europe, South America and Australia. All study participants are above the age of 18 years and are largely recruited from key population subgroups regardless of gender, ethnic background, sexual orientation, political opinion, religious or philosophical conviction. The result is a large cohort that is broadly representative of people living with HIV or people at high risk of acquiring HIV in participating countries.

### 5.2 INCLUSION CRITERIA

1. Have a signed informed consent for the RESPOND consortium and data repository, if required by local/national legislation in order to have data in the common data repository.
2. Signed Informed consent for participation in one or more studies in the RESPOND consortium

3. Age ≥ 18 years

5.3 EXCLUSION CRITERIA
Specific exclusion criteria are defined for each study in RESPOND (for details see protocols for the Outcomes Study and the PrEPare Study).

# 6. RISK FOR PARTICIPANTS

6.1 SAFETY CONSIDERATIONS
No ethical, safety or other related issues have been identified with this collaboration.

Participation in RESPOND and in studies in RESPOND does not include any risk for participants. All studies in the RESPOND consortium are observational studies with collection of information from patient records and where treatment will not be influenced by the studies. The studies in RESPOND does not test any drugs and participation in this study does not interfere with the treatment/care participants may receive at the clinic. Participants remain under the guidance and treatment of their personal physician. Participants do not need to receive ART to participate. Pregnant women may participate in the study, as no interference with their treatment or pregnancy in any way will take place.

# 7. BIOLGICAL MATERIALS

7.1 SAMPLE COLLECTION
Some of the studies in RESPOND collect biological materials in addition to the patient record data. Dried blood spots, whole blood or plasma samples will be collected as part of the patients' standard treatment and not as a specific intervention.

All details on biological sample collection are described in the protocols of the respective studies in RESPOND (for details see protocols for the Outcomes Study and the PrEPare Study).

# 8. INFORMATION FROM PATIENT RECORDS

8.1 PATIENT RECORD DATA
Staff at the sites/cohorts participating in studies in RESPOND will extract data from the patient records of enrolled participants, pseudonymise the data and submit in the Enrolment and FU datasets.

8.2 DATA BASE
Data collected in studies in RESPOND will be pooled and stored in the common RESPOND data repository or 'data lake', which is stored in a database located at CHIP, Rigshospitalet, Copenhagen, Denmark.

# 9. PERSONAL DATA HANDLING AND APPROVALS

## 9.1 CONFIDENTIALITY OF STUDY PARTICIPANTS

The confidentiality of all study participants will be protected in accordance with Good Clinical Practice (GCP) Guidelines and relevant national regulations.

Participants enrolled in the RESPOND collaboration and studies in RESPOND are de-identified and assigned a Unique Patient Identifier (PID). A de-coding list is held in a safe location by the individual site; it is responsibility of cohort PI/local study staff to secure this. All data shared with the coordinating centre contains this PID number. The coordinating centre stores and protects data in accordance with current legislation and under approval by The Danish Data Protection Agency (DK: Datatilsynet), currently under The EU General Data Protection Regulation (EU) 2016/679 (Separate data protection information sheet is handed out to patients, see Annex 1).

The Principal Investigator and other staff at sites/cohorts participating in RESPOND will keep any information and data related to RESPOND and studies in RESPOND provided by the coordinating centre confidential (including this project description) and all data and records generated in the course of conducting the study, and will not use the information, data, or records for any purpose other than conducting the study. These restrictions do not apply to: (1) information which becomes publicly available through no fault of the investigator or study centre personnel; (2) information which it is necessary to disclose in confidence to an International Ethic Committee or Institutional Review Board (IRB) solely for the evaluation of the trial; or (3) information which it is necessary to disclose in order to provide appropriate medical care to a study subject.

## 9.2 REGULATORY APPROVAL

It is the responsibility of each participating site/centre to ensure that all necessary documents and approvals are obtained according to local/national regulations before any study related activities are performed. The PI at each centre/cohort is responsible for obtaining and maintaining this/these approval(s) at all times during the conduct of the study.

RegionH, the legal entity where CHIP is based, is the data protection officer (DPO) for RESPOND and follows the General Data Protection Regulation (GDPR) in Europe. As RESPOND researchers physically are located at different European universities and hospitals, datasets containing information from the participants´ medical records and their biologic samples might be analysed at other locations than the coordinating centre provided that this remains within the appropriate ethics, regulatory and data protection approvals. All RESPOND data is annually sent to the Statistical Center at UCL, London, for statistical analysis.

Participants will in the Informed Consent forms be informed about the above conditions (see section 15).

## 9.3 RECORD RETENTION

When studies in RESPOND close, the PI at the centres will maintain a copy of all site study records in a safe and secure location. CHIP will inform the investigator of the time period for retaining these records.

# 10. ECONOMY AND STUDY ADMINISTRATION

## 10.1 SPONSOR

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

CHIP is the entity that has access to and control over the data in the RESPOND data repository and has the ability to meet all of the requirements for submitting and updating clinical study information.

## 10.2 COLLABORATORS

The RESPOND Scientific Steering Committee is an independent body responsible for overseeing the scientific output of the different data modules, and approving initiation of new specific projects. The SSC comprises 2 co-chairs, representative from coordination center, 1 representative from each cohort submitting data to RESPOND, the leads of active Scientific Interest Group, community representatives, and external experts as agreed by the SSC. This includes researchers, statisticians, clinicians as well as representation from the HIV community.

Studies in the RESPOND consortium will be conducted under the direction of study specific Scientific Interest Group (SIG). The SCC will set up Scientific Interest Groups (SIGs) according to research proposals. As of April 2019, active SIGs are: the Outcomes with ARVs SIG, Hepatitis SIG and the Public Health SIG (for details see protocols for the Outcomes study and the PrEPare study).

## 10.3 FUNDERS

RESPOND 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.

## 10.4 SITE REIMBURSEMENT

The participating sites are reimbursed for completed deliverables, i.e. the relevant CRFs submitted in REDCap and REST and sample shipment if required.

# 11. REMUNERATION AND BENEFITS

## 11.1 STUDY PARTICIPANTS

No remuneration will be paid to the study participants. There are no direct benefits to the study participants. However, the benefit of conducting observational research includes advancing scientific understanding of HIV infection and other related co-infections and co-morbidities and their complications and risk factors for these conditions; this knowledge guides international and European treatment recommendations to the benefit of people living with HIV or at high risk of HIV

# 12. RECRUITMENT AND INFORMED CONSENT

12.1 RECRUITMENT

Participating sites will ask eligible persons living with HIV and/or other infectious diseases or at high risk of HIV to participate in RESPOND and in one or more studies in RESPOND.

The local site Principal Investigator (PI) or his/her designee will inform the participant of all aspects pertaining to his/her participation in RESPOND and the specific study in RESPOND. This is applicable for all studies in the RESPOND consortium in which the person participates (see sample IC in Annex 1).

12.2 INFORMED CONSENT PROCEDURE

The following procedure for obtaining Informed Consent will be followed:

- The participant will prior to study start be informed verbally by a doctor or study nurse about the study and receive written information about the study and about data protection
- The participant will have the opportunity to ask questions
- The participant will be informed that participation is voluntary and that the participant can withdraw his/her consent at any time without any consequence for his/her treatment or future relationship to the clinic/hospital.

When Patient Informed Consent is required by the local/national Ethics Committees or data authorities, this will be obtained from each patient before any study related procedure is performed. Participation in a study in RESPOND also require participation in the RESPOND consortium and data repository. If local/national regulation requires signing of informed consent for the participation in the common data repository, such a consent must be obtained prior to performing any study related procedure.

# 13. PUBLICATIONS

13.1 PUBLICATION AND AUTHORSHIP

The findings from studies in RESPOND, positive, negative or inconclusive, are intended to be published in peer-reviewed journals and/or presented at medical conferences (‘Publication’). Publication will be in accordance with international recognized scientific and ethical standards concerning publications and authorships. Copyrights concerning Publication of the study remain with the authors of the Publication, regardless of any other provisions regarding intellectual property rights.

Authors provide the Coordinating Center with a copy of manuscripts and/or abstracts at least thirty-five (35) business days in advance of any submission for publication and ten (10) business days in advance of any submission to a scientific meeting for approval by the RESPOND SSC (for details on RESPOND see Appendix 1). All publications and presentations from studies in RESPOND will be listed on the CHIP webpage, www.chip.dk, and in the RESPOND eNewsletter sent to all RESPOND Investigators.

# 14. ETHICAL CONSIDERATIONS

## 14.1 ETHICAL CONDUCT OF THE STUDY

The RESPOND consortium and studies in RESPOND will be conducted according to the Declaration of Helsinki in its current version. The requirements of Good Clinical Practice (GCP) as defined in current EU GCP Directive. Human Subject Protection and Data Protection Acts or with the local law and regulation, whichever affords greater protection of human subjects.

# 15 *Sample* Patient Information and Informed Consent

***Sample* RESPOND Patient Information and Informed Consent version 1.0, dated 29 May 2019 for RESPOND Consortium Description Version 1.0 dated 29 May 2019**

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

*Dear Patient,*

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

**What is RESPOND**
RESPOND is a big international collaboration. RESPOND was created to provide a larger and more a uniform platform for conducting studies of infectious diseases with a specific focus on HIV and hepatitis. The RESPOND consortium consists of several studies and all studies in the RESPOND consortium collects data in a consistent but flexible way. All RESPOND survey data is stored in one shared database or 'data lake'. 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 anonymized 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 [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.

**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.

..... ..... ...../...../.....
NAME OF PARTICIPANT SIGNATURE OF PARTICIPANT DATE

..... ..... ...../...../.....
NAME OF RESEARCHER SIGNATURE OF RESEARCHER DATE

## Appendix to IC

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

As a participant in a study in the RESPOND Cohort collaboration, 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 Jakob Friis Larsen
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: respond.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