Appendix to MISTRAL study Informed Consent Form (ICF):

Processing and Protection of your Personal Data based on General Data Protection Regulation (GDPR) Article 13

As a participant in the MISTRAL study, please find below detailed information about processing and protection of your personal data. Your rights in connection with data processing are also described.

Purpose and legal basis for the processing of your personal data

We process your personal data for the purpose described in the ICF. The legal basis for the processing of your personal data is:

• Article 6 and 9 in the General Data Protection Regulation.

Categories of personal data

We only process personal data about you that are described in the ICF.

Processes

We process data about you for the described study purpose. We can share data in a safe way with other study investigators, who are processing data related to the research. The shared data is de-identified. All study investigators follow EU legislation requirements.

What happens to the blood and stool samples?

We will send the blood and stool samples to a central laboratory in Spain. These blood and stool samples will be used to measure your microbiome and other markers of HIV related disease. Any blood or stool left over after these tests will be stored for the duration of the study. Samples will be destroyed the latest on 31st December 2045 in accordance with current legal and ethical requirements. We hope to use these in the future to answer other questions about the microbiome and risk of HIV related complications.

How do we protect your privacy?

We will take every reasonable step to keep your health information private and to keep anyone from misusing it. Your information (data) and samples will not be identified by name, or in any other way, in anything published about this study. We will do everything we can to keep your personal information private. We may have to release your personal information if required by law.

These people may see your medical and research information and are committed to protecting your privacy:

- the Ethics Committee of Clinical Research in each country where research is conducted;
- the sponsor, study research staff and study monitors authorised by the sponsor;
- participating countries' health regulatory agencies, including the staff at the National Scientific Ethics Committee in Denmark, the Danish Data Protection Agency and the Spanish Agency for Medicines and Healthcare Products in Spain;

The data we collect are sent to the Coordinating Centre (CHIP) based in Copenhagen, Denmark where it is stored and quality control assessments are performed. After the quality control, the data will be securely sent to the MISTRAL data repository in Spain where they are kept and analyzed. All study data is marked with a 7-digit Patient ID (PID) number. Date of birth is collected as date, month and year of birth, and no unique person identifiers are present on data submitted to the

Coordinating Centre. We will never give information that can identify you, e.g. your name, address, date of birth or number of your medical records to anybody outside this hospital. The study staff is responsible for protecting any information that can identify you from persons not allowed to access this information.

In the future we will use the samples for analyses that will help us understand more about the microbiome and risk of HIV related complications. You and your doctor will not get the results of these analyses. We will not sell your samples and they will not be used for studies with the purpose of making money (commercial research). The samples will not contain any information that could identify you.

As the research staff at your site, we are required to make sure that people not involved with this study cannot see your research and medical information. We will keep your research files in a safe place and will handle your personal information very carefully.

Your study data are sent electronically to the data server at CHIP and the MISTRAL data repository through a secure system. By signing this consent, you agree to having your data sent to these data repositories. No information that could directly identify you is sent to either CHIP or MISTRAL (the data are sent as de-identified data). Access to the data at these data repositories is limited through security measures, and no data breach or unauthorized access has ever occurred in this system. After the study is over, the data will be stored securely for the period required by law.

Your study data will be shared with the regulatory authorities supervising the studies in accordance with current legislation.

MISTRAL may share your data and specimens with other researchers who study the microbiome and HIV. MISTRAL will delete the PID and date of birth from your data before sharing them. This is called “anonymizing the data” and it will make it impossible for anyone to link the data to you. We will not ask you for additional consent for this sharing. Any external research projects will be assessed for scientific relevance by the MISTRAL Consortium, MISTRAL Scientific Committee formed by MISTRAL partners and EuroSIDA Scientific Steering Committee and will require relevant ethics approval as well as a signed, EU approved, data transfer agreement.

A description of this observational study will be available at http://www.ClinicalTrials.gov and www.chip.dk. As required by Spanish law, a description of this observational study will also be available at http://reec.aemps.es. These websites will not include your name or any other direct identifiers such as your contact information. These websites will include a summary of the results of this research once the study has been completed. You can search the websites at any time.

What are your rights regarding your data?

You decide if we are allowed to collect and use your data. However, you cannot participate in this study if we are not allowed to collect and use your data.

In Spain the current legislation on data protection is the Organic Law 3/2018 of 5 December on Protection of Personal Data and Guaranties of Digital Rights that carries out the EU Regulation 2016/679 (General Data Protection Regulation – GDPR) in Spain.

Transfer to new data controller

If we are contacted by another data controller concerning transfer of project data about you for another purpose than described in this document or in the ICF, we will, before your data are transferred, contact you to get your consent to transfer your data to a new data manager for independent use.

Collection of your personal data
Collection of your personal data is described in the ICF.

Personal data on file
The maximum storage period of data will be until 2045.

The right to withdraw consent
You have the right to withdraw your consent to participate in the study at any time. This can be done by contacting the study team at the clinic.

If you choose to withdraw your consent, it will not affect the legality in us processing your personal data up until the time of the withdrawal. If you withdraw your consent, it will become effective from the date of your withdrawal.

Your rights
According to GDPR you have several rights in respect of our processing of information about you. If you would like to use your rights, please contact the person responsible for the project.

Right to erasure
Regulations apply to statistical and scientific investigations cf. Article 17, paragraph 3, subparagraph d. This means that we can continue to keep and use your personal data already processed. However, all future processing of data will be stopped. If you ask to have your data erased, you will receive a confirmation stating that we will stop processing your data.

Right to transfer information (data portability)
In some cases, you have the right to receive your personal data in a structured commonly used and machine-readable format and to have these personal data transferred from one data controller to another without delay.

There are exceptions to some rights in connection with statistical and scientific investigations, including research
Read more about your rights in the guidelines on rights of registered persons from the Danish Data Protection Agency. The guidelines can be found at www.datatilsynet.dk.

Please note that exceptions are made for several rights in pursuance to § 22, paragraph 5 of GDPR. It concerns Article 15 (Right of Access), Article 16 (Right of Rectification), Article 18 (Right to Restriction of Processing) and Article 21 (Right to Object) of GDPR. This is because all research projects in the Capital Region of Denmark are statistical or scientific investigations of significant importance to community where data processing is necessary due to the investigation cf. Article 89 in GDPR.

Complaints to the Danish Data Protection Agency
You have the right to file a complaint with the Danish Data Protection Agency if you are not content with the way we process your personal data. Contact information for the Danish Data Protection Agency can be found here: https://www.datatilsynet.dk/english

Contact Information

Data Controller

The Capital Region of Denmark acts as data controller in respect of the processing of the personal data we have received about you. Please find contact information below.

The Capital Region of Denmark
Knowledge Center for Data Reviews
Blegdamsvej 9
2100 Copenhagen Ø
Phone: +45 29356799

Email: cru-fp-vfd@regionh.dk

Primary Contact and Coordinating Centre

The primary contact is responsible for the project you are participating in. Please find contact information below:

Professor Jens Lundgren
Rigshospitalet, Department of Infectious Diseases
Blegdamsvej 9
2100 Copenhagen Ø, Denmark
Telephone: +45 35455757
Email: mistral.rigshospitalet@regionh.dk

Contact Information for Data Protection Officer at the Capital Region, Denmark

If you have any questions to our processing of your data in the MISTRAL study, you are always welcome to contact our Data Protection Officer:

Birgitte Hagelskjær Nielsen
Phone: +45 51162935
E-mail : birgitte.hagelskjaer.nielsen@regionh.dk

If you are participating in Denmark, you can also contact our Data Protection Officer using the following link: https://www.regionh.dk/kontakt/henvendelser/Sider/Kontakt-Region-Hovedstadens-databeskyttelsesraadgiver-(DPO).aspx

Contact Information for Data Protection Officer for MISTRAL project at IrsiCaixa, Spain

If you have any questions about how your data will be processed in the MISTRAL project, you are welcome to contact the following:

Julian Eslava
Phone: +34 93 465 63 74
Email: dpo@irsicaixa.es