Informed consent form version 3.0 of 15.02.2021

Information sheet

ANRS CO4 FHDH

* French Hospital Database on the HIV infection

Version no. 3.0 15/02/2021 having received authorization from the CNIL [The French National Data Protection Authority] on 19/02/2021 and having been sent to CEREES [Ethics committee for research, studies and evaluations in the field of health] for information on 09/03/2021

(The previous version named 1.0 received an opinion from CEREES on 20/07/2018)

The person responsible for conducting the data processing is Prof. D. COSTAGLIOLA (Institut Pierre Louis d'Epidémiologie et de Santé Publique, [The Pierre Louis Institute of Epidemiology and Public Health], INSERM, Sorbonne University:

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The data controller is Inserm - ANRS (Institut national de la santé et de la recherche médical [National Institute for health and medical research] (Inserm) - ANRS Maladies Infectieuses Émergentes [ANRS Emerging Infectious Diseases] – An autonomous agency of Inserm) - 101 rue de Tolbiac, 75013 Paris, France

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- **This information sheet is intended to help you make a decision about whether to take part in the study described below. It is important that you read it carefully.**
- **You are free to respond "yes" or "no" when asked the question: "Do you want to take part in the study? "**
- **You have the right to take time to think, to discuss this study and to ask any questions you wish to anyone you choose.**
- **If you do not want to take part, you will continue to receive the best possible care.**
- **You can change your mind at any time and ask to stop taking part in this study. You will continue to benefit from the best care your doctor can offer you. All we ask is that you inform him/her about your decision as soon as possible.**

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Dear Sir or Madam,

Your doctor is inviting you to participate in the study ANRS CO4-FHDH "French Hospital Database on the HIV infection" because you are being monitored in a hospital service that uses a computerized medical records system.

1. OBJECTIVES OF THE STUDY AND LENGTH OF PARTICIPATION

The objective of this study is to study who are the people living with HIV (PLHIV) and receiving hospital care in France, what are their characteristics and the conditions of their care and how these characteristics and conditions evolve over time. Once it has been analyzed, all of these data, will make it possible to evolve and adapt care practices, to improve therapeutic strategies and to assess the efficacy of different treatments better and thus to improve the care of people living with HIV.

This study started in 1989 and has already made it possible to collect data related to 180,000 PLHIV across the whole of France.

Your participation will last throughout the time you are monitored for your HIV infection, unless you advise otherwise. Your data will be stored in accordance with the regulations in force on archiving for research purposes, under conditions that will guarantee its confidentiality.

2. HOW THE STUDY WILL BE CONDUCTED

If you agree to participate in the study, the data from your medical record will be collected then entered on the DOMEVIH software, property of the Ministry of Health, or using the medical records software installed in the hospital service. Once a year, the data from DOMEVIH will be extracted and sent to the IPLESP research team in charge of the database ANRS CO4-FHDH, via a secure transmission gateway. The data will be transmitted in coded form (this means that neither your last name nor your first name will be transmitted by the department providing your care). Particular attention is paid to the confidentiality and security of your data.

You will find below, a list of categories of data relevant to the aim of the study, which will be collected from your medical record:

- Civil status data (in particular sex, date of birth, nationality, the department [county] in which you live)
- Data on the transmission group for HIV and potentially hepatitis
- Health data
- Data on your private life, such as your consumption of tobacco/alcohol or your family situation
- Social data (housing, health insurance) and about your professional life

We wish to clarify that your medical insurance reimbursement data and the pathology codes throughout the entire course of your treatment, relevant to the aim of the study will be collected from the French National Health Data System (Système National des données de santé - SNDS). This data will only be accessible to a limited number of authorized people who have been specially trained at the Pierre Louis Institute of Epidemiology and Public Health (IPLESP, Inserm). It is particularly useful to match the data from the SNDS to your data collected within the context of the ANRS CO4 FHDH study, in order to correct the under-declaration of certain pathologies treated in departments other than those providing the HIV monitoring.

The duration of data storage is set at 50 years for all types of data.

3. INFORMATION DURING AND AFTER THE STUDY

If you wish, you may consult the overall study data and monitor its progress on the website for the ANRS CO4-FHDH study (https://anrs-co4.fhdh.fr).

4. PROCESSING YOUR PERSONAL DATA AND ASSOCIATED RIGHTS

The processing of your personal data within the context of the study ANRS CO4 FHDH will help to fulfil a public interest mission that Inserm-ANRS is invested in and which necessitates the processing of your health data for scientific research purposes.

In accordance with the provisions of the General Data Protection Regulation (Regulation (EU) 2016/679) and the amended Law no. 78-17 of 6 January 1978 on information technology, files and freedoms, you have:

- the right to request access to your data, to have them corrected and deleted,
- the right to object at any time to the collection and use of your data (right to object),
- the right to restrict their use (right to restrict processing)
- the right to withdraw your consent to the research at any time without having to provide justification and without consequences for your treatment. The data related to you will be deleted from the ANRS CO4-FHDH database.

If you wish to exercise these rights, you can speak to the doctor who is supervising you within the context of the research and who alone knows your identity.

If you have any difficulty exercising your rights, you can also contact the Data Protection Officer appointed by Inserm by email (dpo@inserm.fr) or by mail (Data Protection Officer, 101 rue de Tolbiac, 75013 Paris, France).

You also have the right to lodge a complaint with the Commission Nationale de l'Informatique et des Libertés - CNIL, the French supervisory authority for data protection - 3 Place de Fontenoy – TSA 80715, 75334 Paris Cedex 07, France.

Your data (without mentioning your surname and first name) will be accessible to people with special authorization from the team at the Pierre Louis Institute of Epidemiology and Public Health (IPLESP, Inserm) in charge of the ANRS CO4 FHDH database and at the Agence technique de l'information sur l'Hospitalisation [Technical agency for information on Hospitalization] (ATIH).

They may be transferred to the French or foreign health authorities (medicines agency etc.), and to other national or international public research teams, for conducting research, studies or evaluations within the field of health which are of public interest in compliance with the law and according to the appropriate and adapted guarantees ensuring their confidentiality and provided for in a sharing agreement between Inserm-ANRS and the recipient(s) of the data.

You have the right to obtain a copy of the documents linked to the transfer of your data and will be informed of any new study prior to its implementation through the website https://anrs-co4.fhdh.fr.

GLOSSARY

Data: information collected within the context of the study.

Right to restrict processing: the right to temporarily block the use of your data: no data processing operations can be carried out on them.

Coded data: your surname and your first name will be associated with a code that no one knows, neither the doctor, nor the people who have access to your medical data. There is no way to use the code to find the associated person.

Right of access: the right to know about your data and to obtain a copy of them.

Right to object: the right to object to the transmission of your data by the investigating doctor to the sponsor at any time, and to prevent your data from being collected in future. Exercising this right will lead to stopping your participation in the research.

Right to correction: the right to ask for your data to be corrected in the event of an error.

Consent form: the document by which you state that you have understood the procedures for participation in a study and agree to take part in it.

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Data controller: Inserm-ANRS
Person responsible for processing the data: Prof. COSTAGLIOLA Dominique

Mrs./Miss./Ms./Mr. *(last name and first name)* ……..

I hereby certify:
that I have received the information sheet dated **15.02.2021**
that I have had the opportunity to ask all the questions I wanted to about the nature, objectives, the potential risks, and requirements linked to my participation in this study,
that I have had sufficient **time to think** between receiving the information and giving consent.

I have understood the **restrictions** and the **benefits** associated with my participation in this study. My participation will last throughout the time that I am monitored for the HIV infection.
I understand that I am **free to stop taking part** at any time without having to provide a reason, but I will do all I can to inform the doctor who is monitoring me. This will have no negative impact on the quality of my subsequent care.

I have been assured that decisions affecting my health will always be made in accordance with current knowledge on the HIV infection.

I agree to the **data** recorded as part of this study being collected, processed, and digitized. I have understood all of my rights and how to exercise them.

I agree to the scientists involved in this study as well as the authorized partners in France and abroad, and people authorized by the health authorities in France and abroad having **access to the information** in the strictest confidentiality.
My consent in no way releases the organizers of the study from their responsibilities. I retain all **rights afforded by the law**.
During and at the end of the study, I may be informed of the **overall results** by visiting the study website https://anrs-co4.fhdh.fr.

I freely agree to take part in the ANRS CO4 FHDH study under the conditions set out in the information sheet.	
I agree to the use of my data for future research purposes	☐ **YES** ☐ **NO**
On └┴┘ └┴┘ └┴┴┴┘	**Participant's signature:**
I the undersigned, Dr. ..... **hereby certify that I have provided the participant with all of the information about this study, that I have answered his/her questions and obtained his/her consent.**	
On └┴┘ └┴┘ └┴┴┴┘ Department name: Address: Telephone:	**Doctor's signature:**