

Information note to set up a research on data relating to HIV and STIs

Promoter and controller :

Dat'AIDS Association represented by its president Dr Laurent HOCQUELOUX (CHU Orléans) - contact@dataids.org

This document is given to the person taking part in the research.

This information note is available on the www.dataids.org website.

Dear Sir/Madam

The department where you have been or are being treated is actively involved in medical research as part of its public interest mission. Your doctor is now offering you the opportunity to take part in one of these research projects.

The clinical data collected during your treatment (the "Data") may be used by the Dat'AIDS database to conduct non-interventional research, known as "data-based" or "retrospective" research (the "Research(s)"), only recollecting data from your usual follow-up. To this end, the Dat'AIDS association has created a health data warehouse necessary for the purposes of its legitimate interests, i.e. it has set up databases intended to be used for research purposes (the "Database"). The aim of this non-interventional research is to study changes in the treatment and prevention of HIV and other Sexually Transmitted Infections (STIs) in France.

The results of this research are intended to promote the development of scientific knowledge in the management of HIV infection and STIs. The results of the Research may be presented in scientific communications; **under no circumstances will the identity of participants be revealed**. We ensure that results of the Research will under no circumstances allow you to be identified.

As part of each of these researches, your Data is processed electronically. This enables your Data to be analyzed in order to meet the objectives of the Research. Throughout this phase, the confidentiality of your Data is respected, as your identity is encoded by means of a serial number or an alphanumeric code. Only your doctor will be able to match you with your coded identity.

We ensure you that the research complies with the French Data Protection Act of 6 January 1978 as amended and Act No. 2018-493 of 20 June 2018 on the protection of personal data and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (the "GDPR").

The Dat'AIDS association's data warehouse was authorized by the CNIL on 19/06/2024 (decision DT-2024-012).

Data collected

Data collected includes care center, civil status (gender, month and year of birth, country of birth, department of residence), personal life characteristics (family situation, lifestyle habits, level of education), your professional life, your health, sexuality-related characteristics (screening, sexuality, mode of contamination) and your hospital visits (consultation or hospitalization).

We undertake to collect and process only data that is strictly necessary and relevant to the research objectives.

Recipients

The categories of persons described below have access to the Data, within the limits of their functions and under conditions that comply with regulations. These categories of persons are subject to professional medical confidentiality under the conditions defined by articles 226-13 and 226-14 of the French Penal Code.

Will have access to your data:

- the data manager for building the database
- methodologists responsible for data analysis
- the service providers responsible for hosting the data and maintaining the server on which the Data is stored.

This research is being carried out in collaboration with other centers in France (the list of centers is available on dataids.org).

We ensure that our external service providers offer sufficient guarantees regarding the implementation of appropriate technical and organizational measures so that the processing of your Data meets the requirements of the GDPR, the Data Protection Act and guarantees the protection of your rights.

Transfers

No personal data is transferred outside the European Union.

Data retention

Your Data is kept for up to two years after the last publication of the results of the Research or, in the absence of publication, until the end of the Research. Your Data is then archived on a computer medium for a maximum period of fifteen years, after which it is destroyed.

Security

We take all necessary and useful precautions to preserve the security of your Data, in particular its confidentiality, integrity, and availability. Our data storage and sharing service providers are certified (health data host, ISO standard, etc.).

Your rights

In accordance with the provisions of the French Data Protection Act and the GDPR, you have the right to access, rectify, delete, object to, and limit the processing of your Data. The right of access, provided for in Article 15 of the GDPR, may be exercised at any time with the professional involved in the research, either directly or through a doctor designated for this purpose by yourself.

In accordance with the provisions of Article 16 of the GDPR, you have the right to obtain from the controller, as soon as possible, the rectification of inaccurate personal data concerning you and the right to obtain that incomplete personal data be completed, including by providing a supplementary declaration.

If you wish to object to the processing of your personal data for health research, you may, at any time and without having to justify your decision, express your objection by any means to either the person responsible for the research, the participating center or the professional holding the data, in accordance with the French Data Protection Act. This will have no effect on the quality of care you receive. You may also access all your Data directly or through a doctor of your choice, in accordance with the provisions of article L 1111-7 of the French Public Health Code.

The right to erasure (or right to be forgotten) provided for in Article 17 of the GDPR applies when you exercise your right to object and request the erasure of data relating to you that has already been collected. Subject to appropriate prior information by the data controller, certain data previously collected may not, however, be erased if such erasure seriously risks to compromise the achievement of the research objectives. The right to limit processing provided for in Article 18 of the GDPR is exercised in accordance with the provisions of this article.

If you wish to exercise any of your rights, simply inform the Data Protection Officer (the "DPO") of the Dat'AIDS Association at dpo@dataids.org, indicating your care centre.

We undertake to process your request within a maximum of one month from receipt. This period may be extended by two months, depending on the complexity and number of requests. You will be notified of this extension within one month of receipt of the request.

If you are not satisfied with the way we process your Data, you can also lodge a complaint with the CNIL: www.cnil.fr/fr/plaintes).

List of searches

The list of studies linked to this research can be consulted on the dataids.org website, in the "Scientific projects" section.